From:	"Yip, Rebecca (CMS/CM)" <rebecca.yip@cms.hhs.gov>
Sent:	1/17/2024 4:31:54 PM -0500
To:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC:	"Eschliman, Brede (CMS/CM)" <brede.eschliman1@cms.hhs.gov>; "Hendrick, Franklin (CMS/CM)" <Franklin.Hendrick@cms.hhs.gov>; "Morrill, Matt (CMS/CM)" <matthew.morrill@cms.hhs.gov>
BCC:	
Subject:	Januvia Suggestion of Error
Attachments:	FW: [Confidential] Review Requested - Planning Response to CMS Affirming Ceiling Price Calculation

Out of Scope

From:	"Ritter, Christina (CMS/CM)" (b)(6) (b)(6)
Sent:	10/28/2024 12:03:48 PM -0400
To:	"McCormick, Michael (CMS/CM)" <Michael.McCormick@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>
CC:	"Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>
BCC:	
Subject:	FW: FW: Joint CMS / Manufacturer Meeting on MFP Effectuation
Attachments:	Joint CMS _ Manufacturer Meeting on MFP Effectuation.ics; CMS Engagement_MFP Effectuation_10.28_Final.pdf

Out of Scope

Question Report
Report Generated:,"Jan 14, 2025 13:56:02"
Topic,Webinar ID,Actual Start Time,Actual Duration (minutes),# Question
January 2025 Manufacturer Technical Call,160 045 8334,"Jan 14, 2025 12:48:15",60,6
Question Details
#,Question,Asker Name,Asker Email,Answer,Question Time,Answered Time,Answer Name,Answer Email
1,Is the MTF system same as the HPMS gov't system?,John Schaeffer,jschaeff@its.jnj.com,,01/14/2025 13:31:07,,
2,Will MTF modules be made through the MPP portal or separately?,Anonymous Attendee,,,01/14/2025 13:31:57,,
3,For signing of agreements?,John Schaeffer,jschaeff@its.jnj.com,,01/14/2025 13:32:09,,
4,Are these agreements only applicable to manufacturers that have top 10 negotiated drugs?,Anonymous Attendee,,,01/14/2025 13:34:01,,
5,Is the Primary Signatory & Secondary Signatory listed in HPMS will be able to sign the agreements? Or is there going to be a seperate Signatory authorization within the MTF section/website?,Anonymous Attendee,,,01/14/2025 13:39:00,,
6,thank you,Anonymous Attendee,,,01/14/2025 13:40:08,,

From: "Linder, Max (CMS/CM)" <max.linder@cms.hhs.gov>
Sent: 7/9/2024 12:57:54 PM -0400
To: "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>
CC:
BCC:
Subject: Jardiance Meeting Associated Offer Notification

From: CMS IRA Rebate and Negotiation
Sent: Friday, July 5, 2024 10:14 AM
To: christine.marsh@boehringer-ingelheim.com; timmo.andersen@boehringer-ingelheim.com
Subject: Negotiation Meeting 3 Follow-up

Dear Boehringer Ingelheim,

Thank you for attending the third negotiation meeting with CMS on June 21, 2024. As discussed at the end of this meeting, CMS had requested additional time to consider your latest revised counteroffer. After additional consideration, CMS is accepting Boehringer Ingelheim's offer of $197.00 per 30-day equivalent supply for the maximum fair price of Jardiance. Accordingly, CMS has generated a Medicare Drug Price Negotiation Program Agreement Negotiated Maximum Fair Price Addendum ("Addendum") in the CMS Health Plan Management System (HPMS) that reflects this price discussed during our June 21, 2024 meeting. Please log in to the CMS HPMS to review this Addendum. If you decide to sign the Addendum, we are requesting that you do so by Wednesday, July 10, 2024. If signed by Boehringer Ingelheim, it would return to CMS for countersignature via the CMS HPMS, after which the Addendum would be effectuated.

Thank you,
Medicare Drug Rebate and Negotiations Group

From: "Linder, Max (CMS/CM)" <max.linder@cms.hhs.gov>
Sent: 7/9/2024 12:57:02 PM -0400
To: "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>
CC:
BCC:
Subject: Farxiga Meeting Associated Offer Notification

From: CMS IRA Rebate and Negotiation
Sent: Monday, July 8, 2024 9:52 AM
To: Lauzon, Rod <Rod.Lauzon@astrazeneca.com>
Cc: DeNucci, Amanda <amanda.denucci@astrazeneca.com>; Boldt, Matthew <Matthew.Boldt@astrazeneca.com>
Subject: Negotiation Meeting 3 Follow-up

Dear AstraZeneca AB,

Thank you for attending the third negotiation meeting with CMS on June 28, 2024. CMS has received your revised counteroffer shared via Box on July 3, 2024. After consideration of the discussion during the meeting, as well as AstraZeneca AB's revised counteroffer, CMS has decided to accept AstraZeneca AB's most recent revised counteroffer of $178.50 per 30-day equivalent supply for the maximum fair price of Farxiga. Accordingly, CMS has generated a Medicare Drug Price Negotiation Program Agreement Negotiated Maximum Fair Price Addendum ("Addendum") in the CMS Health Plan Management System (HPMS) that reflects this price discussed during our June 28, 2024, meeting. Please log in to the CMS HPMS to review this Addendum. We are requesting that you respond in HPMS by signing the Addendum or rejecting the price by Thursday, July 11, 2024. If signed by AstraZeneca AB, it would return to CMS for countersignature via the CMS HPMS, after which the Addendum would be effectuated.

Thank you,

Medicare Drug Rebate and Negotiations Group

From: "Linder, Max (CMS/CM)" <max.linder@cms.hhs.gov>
Sent: 7/9/2024 12:57:34 PM -0400
To: "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>
CC:
BCC:
Subject: Januvia Meeting Associated Offer Notification

From: CMS IRA Rebate and Negotiation
Sent: Friday, July 5, 2024 10:28 AM
To: Burgess, Breon <breon_burgess@merck.com>; Robinson, Kate <kate.robinson@merck.com>; Seris, Mark <mark_seris@merck.com>
Subject: Negotiation Meeting 3 Follow-up

Dear Merck Sharp Dohme,

Thank you for attending the third negotiation meeting with CMS on June 26, 2024. As discussed at the end of this meeting, CMS had stated that we would continue thinking about the topics we had discussed. After further consideration of the discussion during the meeting, including Merck Sharp Dohme's revised counteroffers, CMS has decided to accept Merck Sharp Dohme's most recent revised counteroffer of $113.00 per 30-day equivalent supply for the maximum fair price of Januvia. Accordingly, CMS has generated a Medicare Drug Price Negotiation Program Agreement Negotiated Maximum Fair Price Addendum ("Addendum") in the CMS Health Plan Management System (HPMS) that reflects this price discussed during our June 26, 2024, meeting. Please log in to the CMS HPMS to review this Addendum. We are requesting that you respond in HPMS by signing the Addendum or rejecting the price by Wednesday, July 10, 2024. If signed by Merck Sharp Dohme, it would return to CMS for countersignature via the CMS HPMS, after which the Addendum would be effectuated.

Thank you,
Medicare Drug Rebate and Negotiations Group

Medicare Drug Rebate and Negotiations Group:

We have thoughtfully considered your communication of November 27, 2024 relating to the following two sentences included on page 23 in our written response and on page 40 in the related attachment that we submitted on November 15, 2024:

"In addition to the different indication, data from the MMIT Formulary bridge shows that

(b)(5)

CMS observed that the clause "In addition to the different indication" is not confidential and that MMIT Formulary bridge is a publicly available source. Based on those observations, our understanding is that CMS is proposing to not redact the underlined text cited above.

We sought to redact the sentences at issue because they reflect Novo Nordisk's confidential analysis of the MMIT data. The stated percentages regarding unrestricted access in Part D described in those sentences are based on the MMIT data but are not publicly available. That information reflects Novo Nordisk's confidential assumptions and analysis of the data.

However, Novo Nordisk has considered CMS's observations relating to the underlined text cited above ("In addition to the different indication," "MMIT Formulary bridge") and we agree with CMS's observations as it relates to that language, narrowly and specifically. We do not have additional information to provide to CMS.

Based on your November 27, 2024 communication that addressed only this issue, our understanding is that CMS otherwise believes that Novo Nordisk has provided sufficient explanations regarding our requests for redactions. We ask that you notify us if that is not the case.

Live Question Log: January 14, 2025 Manufacturer Call on the Implementation of the Medicare Provisions of the IRA

Questions from Stakeholders to CMS

- Is the Medicare Transaction Facilitator (MTF) system the same as the Health Plan Management System (HPMS)? (Johnson & Johnson, question submitted via Zoom Q&A function)
- Will the MTF Data and Payment Modules (DM and PM) be housed on the Manufacturer Payment Portal, or separately? (Anonymous, question submitted via Zoom Q&A function)
- Where will manufacturers sign the MTF Program Agreements? (Johnson & Johnson, question submitted via Zoom Q&A function)
- Are the MTF Program Agreements only applicable to manufacturers whose drugs will be negotiated in IPAY 2026? (Anonymous, question submitted via Zoom Q&A function)
- Does the 14-day prompt MFP payment window include federal holidays? (Teva)
- Are the primary signatory and secondary signatory listed in HPMS able to sign the MTF Program Agreements, or is there going to be a separate signatory authorization within the MTF section and/or website? (Anonymous, question submitted via Zoom Q&A function)
- Can CMS confirm that the MTF Program Agreements do not encompass MFP effectuation for Part B drugs furnished by hospitals and other providers and suppliers? (PhRMA)
- Will CMS commit to affording manufacturers an opportunity to review and provide comments on the draft MTF Program Agreements through a Notice and Comment Process once the IPAY 2028 guidance has been finalized, which will include further details on Part B effectuation? (PhRMA)
- We find the language used in the disclaimer section in the draft MTF Program Agreement between CMS and the Manufacturer broad and concerning. Has this disclaimer language been used in other CMS agreements? (PhRMA)
- From a programmatic perspective, can you help us understand CMS' logic behind providing the MTF Program Agreements on an as-is basis, given that the manufacturers and parties to the agreement will not have visibility into the system requirements and specifications of the MTF, given the Agile process and significant work ahead to develop the MTF and related systems? (Johnson & Johnson)

Questions from CMS to Stakeholders

- None noted.

Meeting Title:	External Call: MFP Effectuation Memo - Johnson & Johnson Worldwide Government Affairs & Policy
From:	"Spangler, Carie (CMS/CM)" <Carie.Spangler@cms.hhs.gov>
Sent:	7/16/2024 1:55:09 PM -0400
To:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Li, Tina (CMS/CM)" <ting.li@cms.hhs.gov>; "Shin, James (CMS/CM)" <james.shin@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Hutchinson, Claire (CMS/CM)" <claire.hutchinson@cms.hhs.gov>; Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>; SMcNama7@its.jnj.com; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; JSchaeff@ITS.JNJ.com; ateeple@ITS.JNJ.com; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>
CC:	
BCC:	
Attendees:	Ritter, Christina (CMS/CM); Garrigan, Thomas (CMS/CM); Daniel, Elisabeth (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Li, Tina (CMS/CM); Shin, James (CMS/CM); Folsom, Brennan (CMS/CM); Hutchinson, Claire (CMS/CM); Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>; SMcNama7@its.jnj.com; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; JSchaeff@ITS.JNJ.com; ateeple@ITS.JNJ.com; Brock, Janet (CMS/CM)
Location:	https://cms.zoomgov.com/ (b)(6) pwd: (b)(6) 1
Start Time:	7/25/2024 3:30:00 PM -0400
End Time:	7/25/2024 4:30:00 PM -0400
Duration:	1 hours
Reminder Time:	7/25/2024 3:15:00 PM -0400
Is Recurring:	false
Recurrence Pattern:	
Busy Status:	Tentative
Attachments:	Final MFP Effectuation Memo.pdf

CARIE Spangler is inviting you to a scheduled ZoomGov meeting.

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833 435 1820 US Toll-free

Meeting ID: (b)(6)

Find your local number: https://cms.zoomgov.com/ (b)(6)

Join by SIP

Password: (b)(6)

sip: (b)(6) @sip.zoomgov.com

This meeting may be recorded. The host is responsible for maintaining any official recordings/transcripts of this meeting. If recorded, this meeting becomes an official record and shall be retained by the host in their files for 3 years or if longer needed for agency business. If a recording intends be fully transcribed or is being captured for the purpose of creating meeting minutes, the host shall retain the record in their files for 3 years or if no longer needed for agency business, whichever is later.

Appointment Title:	Discuss ASP and MDRP Reporting Comment on Draft Negotiation Guidance
Organizer:	Szafara (she/her), Kelly (CMS/CM)
Attendees:	Daniel, Elisabeth (CMS/CM); Garrigan, Thomas (CMS/CM); Ritter, Christina (CMS/CMMI); Strawbridge, Lara (CMS/CMMI); Kennedy, Laura (CMS/CM); Coster, John (CMS/CMCS); Denemark, Cindy (CMS/CMCS); Alemi, Omar (CMS/CMCS); Traugott, Cathy (CMS/CMCS); Morgan, Mickey (CMS/CMCS)
Location:	https://cms.zoomgov.com (b)(6) pwd: (b)(6)
Start Time:	12/16/2024 12:00:00 PM -0500
End Time:	12/16/2024 12:30:00 PM -0500
Reminder Time:	12/16/2024 11:45:00 AM -0500
Reminder Set:	true
Duration:	30 minutes
Is Recurring:	false
Reccurrance Type:	Not
Reccurrance Pattern:	
Response Status:	5
Busy Status:	Tentative
Attachments:	RE: Question on Comment on Treatment of Maximum Fair Price in ASP and MDRP; [71] 7.2.24 Johnson & Johnson Comments on Initial Negotiation Guidance 27.pdf

Out of Scope

Out of Scope

Appointment Title:	External Call: meeting request on formulary access - Amgen
Organizer:	Martin, Kristi (CMS/CM)
Attendees:	Weiss, Rachel (CMS/CM); Hunter, Kaitlin (CMS/CM); Rice, Cheri (CMS/CM); Hutchinson, Claire (CMS/CM); Duran, Vanessa (CMS/CM); Newsom, Mark (CMS/CM); Ritter, Christina (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Daniel, Elisabeth (CMS/CM); Martin, Brian (CMS/CM); Jennifer Young <jyoung@tdyllc.com>; Ahern, Robert (CMS/CM); Mulcahy [he/him], Jerry (CMS/CM); Larsson, Maia (CMS/CM); Gawlik, Yola; McLean, Jenna (CMS/CM); Solomon, Angela (CMS/CM)
Location:	https://cms.zoomgov.com/j/ (b)(6) pwd: (b)(6)
Start Time:	10/7/2024 1:30:00 PM -0400
End Time:	10/7/2024 2:00:00 PM -0400
Reminder Time:	10/7/2024 1:15:00 PM -0400
Reminder Set:	false
Duration:	30 minutes
Is Recurring:	false
Reccurrance Pattern:	
Response Status:	3
Busy Status:	Busy
Attachments:	Meeting Request Form formulary access 240919.doc; Formulary Access to MFP Drugs 241007.pdf

TOPIC:

Amgen would like to discuss CMSâ€™ implementation of the requirement under Section 1860D-4(b)(3)(I) of the Social Security Act, which states that Medicare Part D plans shall include each covered Part D drug that is a selected drug on Part D formularies if a maximum fair price (MFP) is in effect for that drug. Specifically,

- Concerns that Part D plans will move to systematically disadvantage drugs for which an MFP is in effect on their 2026 formularies
- Emerging evidence of access challenges
- Policies that CMS can adopt to ensure beneficiary access to these products in 2026.

External Participants:

CARIE Spangler is inviting you to a scheduled ZoomGov meeting.

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Meeting ID: (b)(6)

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for the purpose of creating meeting minutes, the host shall retain the record in their files for 3 years or if no longer needed for agency business, whichever is later.

Yola Gawlik, Executive Director US Health Policy and Reimbursement

Kelsey Lang, Executive Director US Health Policy and Reimbursement

Jennifer Young, Advisor

Pages 16 through 17 redacted for the following reasons:
- -
(b)(5)

Dear Medicare Drug Rebate and Negotiations Group,

As requested, AbbVie/Pharmacyclics has uploaded to Box a response to the issues raised in your November 27, 2024 correspondence, consistent with your December 6, 2024 email agreeing to a partial extension of the time to respond.

In the interest of acting in good faith to avoid any unnecessary dispute, and while preserving its objections, AbbVie/Pharmacyclics provides the following information in response to the questions set forth in your recent correspondence:

1. **ICR Section I, Question 28, page 7**: other than AbbVie/Pharmacyclics' general objections, outlined in our November 18, 2024 submission and summarized below, AbbVie/Pharmacyclics does not specifically object to redaction of only the second sentence in the selection reproduced in your November 27, 2024 email. (See Page 7 of document - ibrutinib_Imbruvica - MFR E2 Submission AbbVie Pharmacyclics 12-6-Revised).

2. **ICR Section I, Question 32, pages 20-21**: other than AbbVie/Pharmacyclics' general objections, outlined in our November 18, 2024 submission and summarized below, AbbVie/Pharmacyclics does not specifically object to redaction of only the first sentence in the selection reproduced in your November 27, 2024 email. (See Page 20-21 of document - ibrutinib_Imbruvica - MFR E2 Submission AbbVie Pharmacyclics 12-6-Revised).

3. **ICR Section I, Question 29, Page 3**: in addition to AbbVie/Pharmacyclics' general objections, outlined in our November 18, 2024 submission and summarized below, AbbVie/Pharmacyclics believes redaction of the information referenced as citing the two sources listed in your November 27, 2024 is appropriate in addition to redaction of the citations themselves. (See Page 15 of document - ibrutinib_Imbruvica - MFR E2 Submission AbbVie Pharmacyclics 12-6-Revised). All of this information reflects trade secrets or commercial or financial information that is confidential and proprietary and that CMS is barred from disclosing as detailed in our November 18, 2024 submission. AbbVie/Pharmacyclics provided this information to CMS under an assurance that it would be kept confidential and used by CMS only as necessary and required to carry out its authorities established by the Inflation Reduction Act. Public disclosure of this information would harm AbbVie/Pharmacyclics' commercial interests by providing competitors information about prescribing practices and use of the product for approved and unapproved uses. This is highly confidential information, and existence of such data, even by disclosing the data is on file, is prejudicial to AbbVie/Pharmacyclics's commercial interests. Sharing this proprietary information would not only violate the requirements of section 1193(c) of the Social Security Act (the "Act"), but it could also give competitors an unfair advantage. Furthermore, it is unnecessary to disclose to the public how CMS applied the (e)(2) factors to determine the MFP under section 1195(a)(2) of the Act.

While we appreciate the agency's request for additional information with respect to certain discrete objections raised in AbbVie/Pharmacyclics' November 18, 2024 submission, we are concerned that CMS has not responded to the concerns raised in that submission. Nor has CMS responded to our request for pre-disclosure review of any and all additional materials that reference or incorporate AbbVie/Pharmacyclics' information, including the materials AbbVie/Pharmacyclics submitted to CMS in connection with communications and meetings between the parties.

AbbVie/ Pharmacyclics also reiterates and incorporates into this response the objections raised in our earlier correspondence. Those objections include, in brief summary:

- CMS does not have statutory authority to publicize proprietary information submitted by a manufacturer and protected under section 1193(c).

- AbbVie/Pharmacyclics agreed to provide these materials—which as commercially sensitive materials are customarily and actually kept confidential—only because it was required to do so by CMS and with the understanding that the materials would be held in confidence.

- AbbVie/Pharmacyclics' ICR response and other submitted information *as a whole*—including the decision as to what information AbbVie/Pharmacyclics provided in response to CMS's questions—reflects competitively and commercial sensitive proprietary information.

- CMS is required to provide AbbVie/Pharmacyclics with advance notice of *any* information the agency intends to disclose that reflects competitively or commercial sensitive information belonging to AbbVie/Pharmacyclics, but the agency has not done so.

In light of the irreparable harm that will result from disclosure of any confidential information provided to CMS by AbbVie/Pharmacyclics and also to any other competitively or commercial sensitive information belonging to AbbVie/Pharmacyclics, we again renew our requests for pre-disclosure review of *all* materials that CMS intends to publish. We further reiterate our request that you notify us in advance of a specific date on which you intend to disclose any records.

Dear Medicare Drug Rebate and Negotiations Group,

Uploaded to Box, please find AbbVie/Pharmacyclics's response to your letter dated October 18, 2024, which is being submitted consistent with your October 24, 2024, email, which agreed to extend the response deadline to November 18, 2024.

CMS's Legal Authority

Section 1195(a)(2) of the Social Security Act (the "Act"), as added by the Inflation Reduction Act, requires the Centers for Medicare and Medicaid ("CMS") to publish not later than March 1, 2025, "the explanation for the maximum fair price with respect to the factors as applied under section 1194(e) for such drug" selected for price controls for initial price applicability year 2026. That provision is explicitly "subject to section 1193(c)" and does not authorize CMS to publish any other information or materials.

The statute therefore does not permit CMS to publicize proprietary information submitted by a manufacturer and protected under section 1193(c). Indeed, section 1193(c) of the Act permits CMS to use AbbVie/Pharmacyclics's proprietary information only "for purposes of" carrying out that part. Moreover, AbbVie/Pharmacyclics agreed to provide these materials—which as commercially sensitive materials are customarily and actually kept confidential—only because it was required to do so by CMS and with the understanding that the materials would be held in confidence.

CMS should therefore treat the information that AbbVie/Pharmacyclics provided at CMS's direction as proprietary, competitively and commercially sensitive business and trade secret information. Redactions are not appropriate because the information *as a whole*—including the decision as to what information AbbVie/Pharmacyclics provided in response to CMS's questions—reflects competitively and commercial sensitive information, including AbbVie/Pharmacyclics's "negotiation" planning and strategy. Publicly disclosing even a redacted version of the submission would cause AbbVie/Pharmacyclics to suffer substantial and irreparable harm.

In short, CMS should comply with the statute and publish only an explanation of the maximum fair price (and do so in a way that protects AbbVie/Pharmacyclics's proprietary information).

Enclosed Submission

Accompanying this letter is a copy of the responsive documents CMS requested in its October 18 letter. We have provided our proposed changes to CMS's redactions in two formats: (1) we have requested required redactions, un-redactions, and corrections in the provided PDF forms; and (2) we have included a supplemental table, in both Word and .PDF format, which replicates this information in a more reader-friendly format. While preserving its objections, AbbVie/Pharmacyclics has carefully reviewed CMS's proposed redactions and identified additional information in our submission that is closely held highly sensitive information and that must be withheld from any public disclosure. *See* 42 U.S.C. § 1320f-2; 5 U.S.C. § 552(b)(4).

As explained in this submission, AbbVie/Pharmacyclics requests that CMS protect from disclosure information that is proprietary to AbbVie under section 1193(c) of the Act. AbbVie/Pharmacyclics has specifically identified information in its submissions that is proprietary. Per CMS guidance, proprietary information submitted by a manufacturer like AbbVie/Pharmacyclics "will be protected from disclosure" where it "meets the requirements set

forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4))." CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* (Oct. 2., 2024) § 40.2.1.

All of the information that AbbVie/Pharmacyclics has identified for redaction would qualify for one or more exemptions to disclosure in response to any request CMS may receive under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). The information is therefore not appropriately publicly disclosed. Federal agencies do not have discretion to affirmatively disclose trade secrets or privileged or confidential commercial information. *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1186 (D.C. Cir. 2004) (The Trade Secrets Act,18 U.S.C. § 1905, "effectively prohibits" an agency from discretionary release of information exempt from disclosure under FOIA Exemption 4); *see also Sunoco Pipeline, L.P. v. U.S. Dep't of Transp.*, 2023 WL 11195824, at *3 (D.D.C. Sept. 29, 2023) ("An aggrieved party may bring an APA action to enjoin release of information that would violate the Trade Secrets Act").

The enclosed submission details how public disclosure of each category of information AbbVie/Pharmacyclics seeks to protect is proprietary to AbbVie/Pharmacyclics, and how public disclosure would likely result in competitive harm to AbbVie/Pharmacyclics if disclosed by CMS. In many cases, competitors could use confidential information to gain an unfair advantage over AbbVie/Pharmacyclics in the market—for example, by copying proprietary AbbVie/Pharmacyclics processes or integrating proprietary AbbVie/Pharmacyclics information into their own business plans or strategies. Public disclosure under section 1195(a)(2) of proprietary information would also unfairly allow competitors to gain insights into proprietary AbbVie/Pharmacyclics business processes, cost and pricing information, and negotiation strategies.
We also identified a small amount of information that CMS proposed to redact but that should not be redacted because it does not reflect confidential, non-public information and, disclosure of other information, without this non-confidential information, results in a misrepresentation of such information.

We respectfully request that CMS uphold the confidentiality determinations as set forth above and further described in the enclosures. If you disagree with any of our confidentiality designations, we are grateful for your confirmation, as set forth in your November 13 correspondence, that you will provide notice, in writing, "prior to disclosure if the redactions finalized by CMS are inconsistent with any of your requests for redaction or removal of redaction of specific information." We ask that you confirm that you will give us **at least five business days'** notice before publishing any information that disagrees with our proposed changes.

Other Materials and Information

CMS has not provided proposed redactions for any of the materials AbbVie/Pharmacyclics submitted to CMS in connection with communications and meetings between the parties. We assume that is because CMS has stated (in its November 13 email) that it does "not anticipate disclosing any documents that we received from Pharmacyclics that were not described in the pre-disclosure notice." We reiterate what we have stated in all our submission materials: AbbVie/Pharmacyclics considers these materials to be confidential and proprietary non-public information, exempt from disclosure under FOIA.

Please provide us with **at least 10 business days'** opportunity to review any additional materials AbbVie/Pharmacyclics submitted to CMS, if CMS changes its stance and intends to disclose these materials.
In terms of CMS's statement (in its November 13 email) that it "anticipate[s] that additional materials that are not manufacturer-submitted documents will also accompany publication of the MFP explanation":

- AbbVie/Pharmacyclics reiterates that it considers the discussions between CMS and AbbVie, including "offers" and "counteroffers"—including dollar amounts—to be confidential and proprietary non-public information, exempt from disclosure under FOIA.
- AbbVie/Pharmacyclics notes that the names of meeting attendees are personally identifiable information.
- AbbVie/Pharmacyclics notes that the "Ceiling Price Calculation" document CMS sent to AbbVie/Pharmacyclics on December 1, 2023, contains non-public pricing information.

Accordingly, we reiterate our request for **at least 10 business days** to review any additional materials CMS intends to publish, to ensure confidential and proprietary, non-public information is protected per the law.

Additional Notice Requested

We further renew our request that you notify us of a specific date on which you intend to disclose any records, which should come **at least five business days** after written notice is provided to enable us to consider the dispute and determine whether we should seek administrative or judicial remedies. That notification should apply not only to any confidential information provided to CMS by AbbVie/Pharmacyclics but also to any other information you intend to disclose that may have been obtained elsewhere but nonetheless reflects competitively or commercial sensitive information belonging to AbbVie/Pharmacyclics. Because of the irreparable harm that will result from the disclosure of this highly sensitive information, it is important that AbbVie/Pharmacyclics be provided with advance notice of any concerns that CMS might have before any information is publicly disclosed. *Cf.* 45 C.F.R. § 5.42.

NDC-11	Marketed/Controlled by the Primary Manufacturer or a Secondary Manufacturer (Y/N)	Sample Package NDC (Y/N)
50090-3625-00	N	N

Table 18: FARXIGA Tablet Presentations

Tablet Strength	Film-Coated Tablet Color/Shape	Tablet Markings	Package Size	NDC Code
5 mg	yellow, biconvex, round	"5" engraved on one side and "1427" engraved on the other side	Bottles of 30	0310-6205-30
			Bottles of 90	0310-6205-90
10 mg	yellow, biconvex, diamond-shaped	"10" engraved on one side and "1428" engraved on the other side	Bottles of 30	0310-6210-30
			Bottles of 90	0310-6210-90
			Hospital Unit Dose Blister Pack: Carton containing 30 tablets (3 blister cards x 10 tablets per card)	0310-6210-39

Selected Drug Name	NDC-9	Quarter	Medicaid Best Price ($) XCR Submission	Medicaid Best Price ($) Refile [1]	Unit Type	HPMS Refile Submission
STELARA	57894054	Q2 2021	$54.18	$48.92	ML	$48.92
STELARA	57894060	Q2 2021	$9,411.24	$8,851.96	ML	$8,851.96
STELARA	57894061	Q2 2021	$9,411.24	$9,583.15	ML	$9,583.15
XARELTO	504580577	Q2 2021	$3.23	$3.28	TAB	$3.28
XARELTO	504580578	Q2 2021	$6.47	$6.57	TAB	$6.57
XARELTO	504580579	Q2 2021	$6.47	$6.57	TAB	$6.57
XARELTO	504580580	Q2 2021	$6.47	$6.57	TAB	$6.57
XARELTO	504580584	Q2 2021	$6.47	$6.57	TAB	$6.57
STELARA	57894054	Q3 2021	$54.72	$49.93	ML	$49.93
STELARA	57894060	Q3 2021	$9,411.24	$8,881.96	ML	$8,881.96
STELARA	57894061	Q3 2021	$9,411.24	$9,613.15	ML	$9,613.15
XARELTO	504580577	Q3 2021	$3.23	$3.28	TAB	$3.28
XARELTO	504580578	Q3 2021	$6.47	$6.57	TAB	$6.57
XARELTO	504580579	Q3 2021	$6.47	$6.57	TAB	$6.57
XARELTO	504580580	Q3 2021	$6.47	$6.57	TAB	$6.57
XARELTO	504580584	Q3 2021	$6.47	$6.57	TAB	$6.57

Current through April 02, 2024

You have searched Finished drug products

Search Results: *'xarelto'*

Back to Search Page () | **Search Again ()**

CSV | Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
– Xarelto	50090-3625-0	10 mg/1	TABLET, FILM COATED	ORAL	NDA022406	A-S Medication Solutions	50090-3625	rivaroxaban	RIVAROXABAN	HUMAN PRESCRIPTION DRUG	10/06/2018	N/A	NDA	90 TABLET, FILM COATED in 1 BOTTLE (50090-3625-0)	Factor Xa Inhibitor [EPC], Factor Xa Inhibitors [MoA]

DEA N/A

Sample Package No

Listing Record Certified Through: 12/31/2024

Proprietary

Merck Sharp & Dohme LLC
P.O. Box 1000, UG4AB-15 351 North
Sumneytown PikeNorth Wales, PA 19454

September 11, 2023

Via Email to: HPMSConsultantAccess@cms.hhs.gov

Re: REQUEST FOR HPMS SIGNATORY ACCESS

Dear CMS,

Merck Sharp & Dohme LLC hereby requests that the following two individuals be granted electronic signature access in HPMS:

- **Ms. Kate Robinson**, Vice President of Integrated Account Management (CMS userid: **RTH0**)
- **Ms. Breon Burgess**, Vice President of Finance (CMS userid: **BVR7**)

Below are the P-numbers for which this electronic signature access is required:

- **P1004** - Merck Sharp & Dohme LLC
- **P1154** - Cubist Pharmaceuticals, Inc
- **P1176** - Inspire Pharmaceuticals, Inc.

Sincerely,

Caroline Litchfield
Chief Financial Officer
Merck Sharp & Dohme LLC

9				Scott Watson	scott.watson@bms.com	Signatory User and Primary POC
0	ENBREL	IMMUNEX CORPORATION [Amgen]	P1177	Anton Rabushka	antonr@amgen.com	Signatory User
1				Matthew Busch	mbusch@amgen.com	Signatory User
2				Jill Farkas	jfarkas@amgen.com	Primary POC
3	STELARA	JANSSEN BIOTECH, INC.	P1243	John Schaeffer	jschaeff@its.jnj.com	Signatory User
4				Lee Blevins	lblevins@its.jnj.com	Signatory User
5				Glen Huttar	ghuttar@its.jnj.com	Primary POC
6				John Fela	jfela@its.jnj.com	Primary POC
7				Laura D'Meza	ldmeza@its.jnj.com	Primary POC
8	XARELTO	JANSSEN PHARMS	P1135	John Schaeffer	jschaeff@its.jnj.com	Signatory User
9				Lee Blevins	lblevins@its.jnj.com	Signatory User
0				Glen Huttar	ghuttar@its.jnj.com	Primary POC
1				John Fela	jfela@its.jnj.com	Primary POC

9				Scott Watson	scott.watson@bms.com	Signatory User and Primary POC
0	ENBREL	IMMUNEX CORPORATION [Amgen]	P1177	Anton Rabushka	antonr@amgen.com	Signatory User
1				Matthew Busch	mbusch@amgen.com	Signatory User
2				Jill Farkas	jfarkas@amgen.com	Primary POC
3	STELARA	JANSSEN BIOTECH, INC.	P1243	John Schaeffer	jschaeff@its.jnj.com	Signatory User
4				Lee Blevins	lblevins@its.jnj.com	Signatory User
5				Glen Huttar	ghuttar@its.jnj.com	Primary POC
6				John Fela	jfela@its.jnj.com	Primary POC
7				Laura D'Meza	ldmeza@its.jnj.com	Primary POC
8	XARELTO	JANSSEN PHARMS	P1135	John Schaeffer	jschaeff@its.jnj.com	Signatory User
9				Lee Blevins	lblevins@its.jnj.com	Signatory User
0				Glen Huttar	ghuttar@its.jnj.com	Primary POC
1				John Fela	jfela@its.jnj.com	Primary POC

9				Scott Watson	scott.watson@bms.com	Signatory User and Primary POC
0	ENBREL	IMMUNEX CORPORATION [Amgen]	P1177	Anton Rabushka	antonr@amgen.com	Signatory User
1				Matthew Busch	mbusch@amgen.com	Signatory User
2				Jill Farkas	jfarkas@amgen.com	Primary POC
3	STELARA	JANSSEN BIOTECH, INC.	P1243	John Schaeffer	jschaeff@its.jnj.com	Signatory User
4				Lee Blevins	lblevins@its.jnj.com	Signatory User
5				Glen Huttar	ghuttar@its.jnj.com	Primary POC
6				John Fela	jfela@its.jnj.com	Primary POC
7				Laura D'Meza	ldmeza@its.jnj.com	Primary POC
8	XARELTO	JANSSEN PHARMS	P1135	John Schaeffer	jschaeff@its.jnj.com	Signatory User
9				Lee Blevins	lblevins@its.jnj.com	Signatory User
0				Glen Huttar	ghuttar@its.jnj.com	Primary POC
1				John Fela	jfela@its.jnj.com	Primary POC

From:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent:	3/1/2024 12:59:21 PM -0500
To:	"Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Li, Tina (CMS/CM)" <ting.li@cms.hhs.gov>
CC:	"Hunter, Kaitlin (CMS/CM)" <Kaitlin.Hunter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>
BCC:	
Subject:	FW: FW: CMS "Counteroffer"

Out of Scope

From: Penkowski, Blasine [SCGUS] <bpenkows@ITS.JNJ.com>
Sent: Friday, March 1, 2024 12:50 PM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Subject: CMS "Counteroffer"

Dear Dr. Seshamani,

Today, In accordance with section 1194(b)(2)(C) of the Social Security Act (the Act), Janssen Pharmaceuticals, Inc. and Janssen Biotech, Inc. (together, "Janssen") submitted and certified the "counteroffer" and justification to CMS within the HPMS portal.

Janssen's use of CMS's or statutory terminology (e.g., "counteroffer," "Maximum Fair Price") does not reflect Janssen's agreement that such terminology is accurate. As set forth in Janssen's October 2, 2023 letter to CMS, Janssen does not agree that participation in the

Drug Price Negotiation Program is voluntary or compliant with the First or Fifth Amendments of the U.S. Constitution."

Janssen reserves all rights with respect to the Drug Price Negotiation Program, including the rights asserted in our litigation filing. Please include this message in the record of the CMS proceedings with respect to Janssen's selected drugs XARELTO® and STELARA®.

Sincerely,

Blasine Penkowski

Blasine Penkowski

Blasine Penkowski

Chief Strategic Customer Officer

Janssen North America

bpenkows@its.jnj.com

847-951-5258

Appointment Title:	External Call: BMS-CMS Meeting on MTF/MFP Effectuation
Organizer:	Martin, Kristi (CMS/CM)
Attendees:	Rice, Cheri (CMS/CM); Ahern, Robert (CMS/CM); Ritter, Christina (CMS/CM); Tucker, Caroline <Caroline.Tucker@bms.com>; Brock, Janet (CMS/CM); McCormick, Michael (CMS/CM); Folsom, Brennan (CMS/CM); Garrigan, Thomas (CMS/CM); Daniel, Elisabeth (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Stuart (MDRNG), Eric J (CMS/CM); Deal, James; Kamin, Linda
Location:	https://cms.zoomgov.com/j/ (b)(6) pwd (b)(6) 1
Start Time:	8/7/2024 12:30:00 PM -0400
End Time:	8/7/2024 1:00:00 PM -0400
Reminder Time:	8/7/2024 12:15:00 PM -0400
Reminder Set:	false
Duration:	30 minutes
Is Recurring:	false
Reccurrance Pattern:	
Response Status:	1
Busy Status:	Busy
Attachments:	BMS Comments-IPAY 2027_Final.pdf; image001.png

CARIE Spangler is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

https://cms.zoomgov.com/ (b)(6) pwd: (b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

+16692545252,, US (San Jose)

+16468287666,, (b)(6) US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

+1 646 828 7666 US (New York)

833 568 8864 US Toll-free

833 435 1820 US Toll-free

Meeting ID: (b)(6)

Find your local number: https://cms.zoomgov.com, (b)(6)

Join by SIP

Password: (b)(6)

sip: (b)(6) @sip.zoomgov.com

This meeting may be recorded. The host is responsible for maintaining any official recordings/transcripts of this meeting. If recorded, this meeting becomes an official record and shall be retained by the host in their files for 3 years or if longer needed for agency business. If a recording intends be fully transcribed or is being captured for the purpose of creating meeting minutes, the host shall retain the record in their files for 3 years or if no longer needed for agency business, whichever is later.

Hi Kristi,

I hope this email finds you well! If you remember, the BMS team came in a few times last year to talk through MFP effectuation, and now that our comment letter has been submitted (attached for your reference) and we've been able to think on the topic more, we'd love to come in and talk with the CMS team again and share our experiences. Do you and your colleagues have time in late July to discuss? Perhaps the week of the 22nd or 29th? An hour would be great, because we have a lot of topics to discuss related to the MTF and MFP effectuation, but we know you're busy and would be happy to accommodate your schedule. Also, if there's anything specific you'd like us to be prepared to discuss, please do let us know.

Thanks so much in advance, and looking forward to connecting again soon! Let us know if you have any questions or concerns.

Thanks,

Caroline

Caroline P. Tucker

Director | Executive Branch Strategy

US Policy & Government Affairs

Email: caroline.tucker@bms.com

Mobile: (b)(6)

September 13, 2023

Dear CMS HPMS Access Team,

Re: Manufacturer Electronic Signature Access - Novo Nordisk Inc. (P1029) & Novo Nordisk Pharma Inc (P1705)

As the Chief Financial Officer for Novo Nordisk Inc and Novo Nordisk Pharma, Inc., I hereby request that CMS grant Drug Price Negotiation Signatory Access (Access code 2154) to the following authorized representatives who have been delegated authority to perform electronic signatures on my behalf for the Medicare Drug Price Negotiation Program:

Farruq Jafery (CMS User ID: J328)
VP, Pricing, Contract Ops & Reimbursement
Ph: 609-578-9049
Email: faja@novonordisk.com

Michael Henricksen (CMS User ID: HC5I)
Sr. Director, Strategic Pricing & Contracting
Ph: 609-578-8320
Email: mlhc@novonordisk.com

Novo Nordisk Inc. & Novo Nordisk Pharma, Inc.

Ulrich Christian Otte
Chief Financial Officer & Senior VP, Finance & Operations

From:	"Ritter, Christina (CMS/CM)" (b)(6) (b)(6)
Sent:	12/18/2024 12:51:18 PM -0500
To:	"Yip, Rebecca (CMS/CM)" <rebecca.yip@cms.hhs.gov>; "Eschliman, Brede (CMS/CM)" <brede.eschliman1@cms.hhs.gov>; "Hendrick, Franklin (CMS/CM)" <Franklin.Hendrick@cms.hhs.gov>
CC:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>
BCC:	
Subject:	FW: FW: BMS: Requested Follow-up from 12/10 Meeting
Attachments:	image001.png

From: Tucker, Caroline <Caroline.Tucker@bms.com>
Sent: Wednesday, December 18, 2024 12:32 PM
To: Weiss, Rachel (CMS/CM) <rachel.weiss@cms.hhs.gov>; Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>; Coster, John (CMS/CM) <John.Coster@cms.hhs.gov>; Li, Tina (CMS/CM) <ting.li@cms.hhs.gov>; Hunter, Kaitlin (CMS/CM) <Kaitlin.Hunter@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>
Cc: Verb, Katie <Katie.Verb@bms.com>; Knott, William <William.Knott@bms.com>
Subject: BMS: Requested Follow-up from 12/10 Meeting

FOIA EXEMPT – CONFIDENTIAL INFORMATION – NOT FOR PUBLIC DISCLOSURE

Hi all, please find the requested follow-up from our meeting last week below. I'm sharing with those on the calendar invite, but please share with others on the call we might have missed.

Thank you for meeting with us on December 10 to discuss the policy and market access reasons why our drug Pomalyst should not be selected during the IPAY 2027 selection process. As discussed, Pomalyst is a convenient, oral standard of care immunomodulatory drug (IMiD) used in the treatment of relapsed refractory multiple myeloma (RRMM) and Kaposi Sarcoma (KS). Based on both confidential internal and public external assessments, Pomalyst is expected to lose exclusivity in Q1 2026, with six generic products expected to enter the market in Q1 2026 and nine generic products expected to enter the market by the end of 2026. The number of generic competitors points to significant anticipated market erosion. It is likely that plans will prioritize generics over Pomalyst through utilization management, and branded Pomalyst will potentially be removed from formulary altogether in 2H 2026. We believe CMS will not benefit from Pomalyst's selection over true single

source, high-expenditure products due to the rapid market erosion and shift to generic alternatives.

In our meeting, you requested our thoughts on legal authority to make such a determination in your selection process. We note first that under Subsections 1192(d)(1) and 1192(b)(1), the process entails (1) a determination that a drug is "among the 50 qualifying single source drugs [QSSDs] with the highest total expenditures" under Medicare Part D; (2) a ranking of the 50 highest expenditure drugs "as determined by the Secretary"; and then (3) selection of highest-ranking drugs "from" that ranking. This text provides the Agency with discretion in selection; it can choose to select one of the highest ranked drugs other than Pomalyst in this round. Were it otherwise, then the provision requiring a determination that a drug is among the 50 QSSDs and the overarching ranking of many more drugs than the 15 that must be selected would appear superfluous. Additionally, the provision of a "selection" process itself suggests that CMS has some measure of discretion to pick from the list of negotiation-eligible drugs. The plain meaning of the word "select" implies judgment, rather than a rote counting exercise. The definition of a "selected drug" emphasizes the Secretary's (and by extension CMS') role in determining the ranking ("as determined by the Secretary"), indicating a degree of discretion.

Further, when the innovator product will face generic competition before the IPAY begins, CMS can exercise its discretion to make a determination that the product is ineligible for selection due to the generic competition. Here, before January 1, 2027, Pomalyst will no longer meet the definition of a QSSD, a necessary predicate to meeting the definition of a negotiation-eligible drug and a selected drug, before the first day of IPAY 2027. Section 1192(e)(1)(A)(iii) provides that a drug is not a QSSD upon marketing of a generic drug for which it is the listed drug under section 505(j) of the FDCA, without imposing a time limitation on this condition. This, along with language defining a QSSD "with respect to an [IPAY]" indicates that Congress contemplated that CMS could consider whether a drug will still meet the definition of a QSSD on the first day of the IPAY.

The provisions above all support the Secretary using appropriate judgment in the selection process to choose the drugs that will best fulfill the statute's purpose. Further, CMS' selection decision is not subject to judicial review. Selecting Pomalyst would reduce CMS' opportunity to promote overall greater cost savings for the Medicare program and patients. Given the circumstances of Pomalyst as likely subject to generic competition before an MFP goes into effect on January 1, 2027, CMS should exercise discretion in the selection of products and not choose Pomalyst for IPAY 2027.

We hope these thoughts are helpful and appreciate your time and consideration.

Thank you and happy holidays!!!

Caroline & the BMS Team

Caroline P. Tucker

Director | Executive Branch Strategy

US Policy & Government Affairs

Email: caroline.tucker@bms.com

Mobile: (b)(6)

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abbvie

pharmacyclics
An AbbVie Company

Department of Health and Human Services
Centers for Medicare & Medicaid Services, Health Plan Management System
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: HPMSConsultantAccess@cms.hhs.gov

September 11, 2023

To Whom it May Concern:

As described in the memoranda issued by CMS on May 4, 2023 and August 21, 2023, I am requesting that the following individuals be granted electronic signature access (access type Drug Price Negotiation Signatory Access - Manufacturer (2154)) for the following P number: P1396

- Michael C. Staff, Vice President, Inflation Reduction Act Product and Channel Strategies (HPMS user ID SJ6O)
- Latif Akintade, Senior Vice President, Medical Affairs and HEOR (HPMS user ID A0VP)

Please reach out with any questions.

Sincerely,

Scott T. Reents
Executive Vice President, Chief Financial Officer, AbbVie Inc.
President, Pharmacyclics, LLC

cc: Michael C. Staff, Michael.Staff@abbvie.com
Latif Akintade, Latif.Akintade@abbvie.com

From:	"Roche, Jacqueline [JJCUS]" <jroche8@its.jnj.com>
Sent:	7/11/2024 3:23:59 PM -0400
To:	"Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Weiss, Rachel (CMS/CM)" <rachel.weiss@cms.hhs.gov>
CC:	"Schaeffer, John [HCSUS]" <JSchaeff@ITS.JNJ.com>; "Hancock, Rebecca [JJCUS]" <RHancoc1@ITS.JNJ.com>; "Teeple, Amanda [JRDUS]" <ateeple@ITS.JNJ.com>
BCC:	
Subject:	Re: Re: Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation

Also including Rachel! (Kristy I received your OOO).

Thanks CMS team,
Jackie

From: Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>
Sent: Thursday, July 11, 2024 3:22 PM
To: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina S. (CMS/CMMI) <Christina.Ritter@cms.hhs.gov>
Cc: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; Teeple, Amanda [JRDUS] <ateeple@ITS.JNJ.com>
Subject: Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation

Hi, Kristi and Chris: Thank you for meeting with the &J team on June 20, 2024 to discuss the MFP effectuation. We greatly appreciate the opportunity to collaborate and share our recommendations. We strongly advocate for continued collaboration between our organizations, aiming for successful MFP effectuation through a structured cadence of regular meetings.

We have been advancing the three requests outlined during that discussion:

1. MFP Effectuation/Implementation Requirements
2. Assessing Legal authority to pre-fund the program
3. Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation

We continue to make progress on the first two items and have shared documents from our previous meeting that outline five requirements for effectuation as well as the legal basis for floating on behalf of CMS. In an upcoming communication we intend to share a deep-dive into the claim validation process. (and other metrics related to 340B verification, etc.)

To incorporate an aligned coalition perspective, we are proposing a joint session with CMS, the manufacturers affected by IPAY 2026/27 and a pharmacy stakeholder group. Our goal is to compliantly bring these stakeholders together to share industry insights, expedite decision-making, and to ensure that the final guidance represents a solution that is workable across the ecosystem players. Could you please advise when CMS would like to schedule this session? We suggest mid-August 2024 to maintain continued progress.

We look forward to your response and to continuing our productive collaboration.

Best regards,

Jackie

From: Roche, Jacqueline [JJCUS]
Sent: Friday, June 21, 2024 3:23 PM
To: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina S. (CMS/CMMI) <Christina.Ritter@cms.hhs.gov>; Coster, John (CMS/CMCS) <John.Coster@cms.hhs.gov>; michael.mccormick@cms.hhs.gov <michael.mccormick@cms.hhs.gov>; janet.brock2@cms.hhs.gov <janet.brock2@cms.hhs.gov>
Cc: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; Teeple, Amanda [JRDUS] <ateeple@ITS.JNJ.com>
Subject: MFP Effectuation _ J&J Follow-up

Hi, Team CMS: Thank you for the meeting yesterday with our cross-functional J&J team regarding MFP effectuation. We greatly appreciate the opportunity to collaborate and share our MFP effectuation recommendations. J&J will continue to guide this important collaboration with stakeholders since an end-to-end solution is important for supply chain integrity.

We didn't quite get there yesterday, but we strongly recommend the formulation of a governance structure among our teams to integrate our workflows, align to decisions on the critical path, etc., leading up to 1.1.26 "go live."

Attached to this email, you will find the deck we shared yesterday. The deck focused on various elements of MFP effectuation, including five critical requirements for MFP effectuation and supplementary information to support the role of these requirements. The five critical requirements we recommend are CMS Pre-funding, Mandatory use of MTF (end-to-end solution facilitating payment and data-sharing), 340 B Data transparency, 45 Day Manufacturer Process for validation and compliance processes, and Transparent Dispute/Appeals operations.

Additionally, J&J is currently developing the following:

- Legal Authority Resources (Goal: Share with CMS early next week)
- Internal business requirements for claims validation and timeline specific to MFP
- Metrics to demonstrate the scale and potential impact of reversals, duplicates, and 340B

Continued Collaboration:

- We propose the development of a collaborative governance model to jointly develop workable solutions to effectuate MFP on 1/1/26
- We recommend meeting bi-weekly to continue to jointly assess solutions

It is critical that decisions be made urgently regarding CMS Pre-Funding and the role and capabilities of the MTF to allow the appropriate infrastructure to be built for a 1/1/26 go-live. Please let us know the next available date the CMS team is available to meet to continue our conversation.

Thank you again, and we look forward to putting these next steps into action,

Have a nice weekend, my apologies I didn't have TJ's email.

Jackie

Jacqueline Roche
Head Payment and Delivery & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy WWGA&P
Mobile: (b)(6)
Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

Meeting Title:	External Call: BMS-CMS Meeting on MTF/MFP Effectuation
From:	"Spangler, Carie (CMS/CM)" <Carie.Spangler@cms.hhs.gov>
Sent:	7/23/2024 5:52:57 PM -0400
To:	"Rice, Cheri (CMS/CM)" <Cheri.Rice@cms.hhs.gov>; "Ahern, Robert (CMS/CM)" <Robert.Ahern@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; Tucker, Caroline <Caroline.Tucker@bms.com>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "McCormick, Michael (CMS/CM)" <Michael.McCormick@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Stuart (MDRNG), Eric J (CMS/CM)" <eric.stuart@cms.hhs.gov>
CC:	
BCC:	
Attendees:	Rice, Cheri (CMS/CM); Ahern, Robert (CMS/CM); Ritter, Christina (CMS/CM); Tucker, Caroline <Caroline.Tucker@bms.com>; Brock, Janet (CMS/CM); McCormick, Michael (CMS/CM); Folsom, Brennan (CMS/CM); Garrigan, Thomas (CMS/CM); Daniel, Elisabeth (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Stuart (MDRNG), Eric J (CMS/CM)
Location:	https://cms.zoomgov.com/ (b)(6) pwd= (b)(6) 1
Start Time:	8/7/2024 12:30:00 PM -0400
End Time:	8/7/2024 1:00:00 PM -0400
Duration:	30 minutes
Reminder Time:	8/7/2024 12:15:00 PM -0400
Is Recurring:	false
Recurrence Pattern:	
Busy Status:	Tentative
Attachments:	BMS Comments-IPAY 2027_Final.pdf; image001.png

CARIE Spangler is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

https://cms.zoomgov.com/ (b)(6) pwd= (b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

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Dial by your location

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This meeting may be recorded. The host is responsible for maintaining any official recordings/transcripts of this meeting. If recorded, this meeting becomes an official record and shall be retained by the host in their files for 3 years or if longer needed for agency business. If a recording intends be fully transcribed or is being captured for the purpose of creating meeting minutes, the host shall retain the record in their files for 3 years or if no longer needed for agency business, whichever is later.

Hi Kristi,

I hope this email finds you well! If you remember, the BMS team came in a few times last year to talk through MFP effectuation, and now that our comment letter has been submitted (attached for your reference) and we've been able to think on the topic more, we'd love to come in and talk with the CMS team again and share our experiences. Do you and your colleagues have time in late July to discuss? Perhaps the week of the 22nd or 29th? An hour would be great, because we

have a lot of topics to discuss related to the MTF and MFP effectuation, but we know you're busy and would be happy to accommodate your schedule. Also, if there's anything specific you'd like us to be prepared to discuss, please do let us know.

Thanks so much in advance, and looking forward to connecting again soon! Let us know if you have any questions or concerns.

Thanks,

Caroline

Caroline P. Tucker

Director | Executive Branch Strategy

US Policy & Government Affairs

Email: caroline.tucker@bms.com

Mobile: (b)(6)

From:	"Roche, Jacqueline [JJCUS]" <jroche8@its.jnj.com>
Sent:	7/11/2024 3:23:59 PM -0400
To:	"Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Weiss, Rachel (CMS/CM)" <rachel.weiss@cms.hhs.gov>
CC:	"Schaeffer, John [HCSUS]" <JSchaeff@ITS.JNJ.com>; "Hancock, Rebecca [JJCUS]" <RHancoc1@ITS.JNJ.com>; "Teeple, Amanda [JRDUS]" <ateeple@ITS.JNJ.com>
BCC:	
Subject:	Re: Re: Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation?

Also including Rachel! (Kristy I received your OOO).

Thanks CMS team,
Jackie

From: Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>
Sent: Thursday, July 11, 2024 3:22 PM
To: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina S. (CMS/CMMI) <Christina.Ritter@cms.hhs.gov>
Cc: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; Teeple, Amanda [JRDUS] <ateeple@ITS.JNJ.com>
Subject: Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuationâ€‹

Hi, Kristi and Chris: Thank you for meeting with the &J team on June 20, 2024 to discuss the MFP effectuation. We greatly appreciate the opportunity to collaborate and share our recommendations. We strongly advocate for continued collaboration between our organizations, aiming for successful MFP effectuation through a structured cadence of regular meetings.â€‹
â€‹
We have been advancing the three requests outlined during that discussion:â€‹

1. MFP Effectuation/Implementation Requirements
2. Assessing Legal authority to pre-fund the programâ€‹
3. Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuationâ€‹

We continue to make progress on the first two items and have shared documents from our previous meeting that outline five requirements for effectuation as well as the legal basis for floating on behalf of CMS. In an upcoming communication we intend to share a deep-dive into the claim validation process. (and other metrics related to 340B verification, etc.)
â€‹
To incorporate an aligned coalition perspective, we are proposing a joint session with CMS, the manufacturers affected by IPAY 2026/27 and a pharmacy stakeholder group. Our goal is to compliantly bring these stakeholders together to share industry insights, expedite decision-making, and to ensure that the final guidance represents a solution that is workable across the ecosystem players. Could you please advise when CMS would like to schedule this session? We suggest mid-August 2024 to maintain continued progress. â€‹

â€‹
We look forward to your response and to continuing our productive collaboration.â€‹
â€‹
Best regards,

Jackie

From: Roche, Jacqueline [JJCUS]
Sent: Friday, June 21, 2024 3:23 PM
To: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina S. (CMS/CMMI) <Christina.Ritter@cms.hhs.gov>; Coster, John (CMS/CMCS) <John.Coster@cms.hhs.gov>; michael.mccormick@cms.hhs.gov <michael.mccormick@cms.hhs.gov>; janet.brock2@cms.hhs.gov <janet.brock2@cms.hhs.gov>
Cc: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; Teeple, Amanda [JRDUS] <ateeple@ITS.JNJ.com>
Subject: MFP Effectuation _ J&J Follow-up

Hi, Team CMS: Thank you for the meeting yesterday with our cross-functional J&J team regarding MFP effectuation. We greatly appreciate the opportunity to collaborate and share our MFP effectuation recommendations. J&J will continue to guide this important collaboration with stakeholders since an end-to-end solution is important for supply chain integrity.

We didn't quite get there yesterday, but we strongly recommend the formulation of a governance structure among our teams to integrate our workflows, align to decisions on the critical path, etc., leading up to 1.1.26 "go live."

Attached to this email, you will find the deck we shared yesterday. The deck focused on various elements of MFP effectuation, including five critical requirements for MFP effectuation and supplementary information to support the role of these requirements. The five critical requirements we recommend are CMS Pre-funding, Mandatory use of MTF (end-to-end solution facilitating payment and data-sharing), 340 B Data transparency, 45 Day Manufacturer Process for validation and compliance processes, and Transparent Dispute/Appeals operations.

Additionally, J&J is currently developing the following:

- Legal Authority Resources (Goal: Share with CMS early next week)
- Internal business requirements for claims validation and timeline specific to MFP
- Metrics to demonstrate the scale and potential impact of reversals, duplicates, and 340B

Continued Collaboration:

- We propose the development of a collaborative governance model to jointly develop workable solutions to effectuate MFP on 1/1/26
- We recommend meeting bi-weekly to continue to jointly assess solutions

It is critical that decisions be made urgently regarding CMS Pre-Funding and the role and capabilities of the MTF to allow the appropriate infrastructure to be built for a 1/1/26 go-live. Please let us know the next available date the CMS team is available to meet to continue our conversation.

Thank you again, and we look forward to putting these next steps into action,

Have a nice weekend, my apologies I didn't have TJ's email.

Jackie

Jacqueline Roche
Head Payment and Delivery & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy WWGA&P
Mobile: (b)(6)
Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

From:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>
Sent:	12/16/2024 9:07:00 AM -0500
To:	"Kane, Corden (CMS/CM)" <corden.kane2@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Boone, Chanelle (CMS/CM)" <Chanelle.Boone@cms.hhs.gov>; "Lynn, Nicholas (CMS/CM)" <nicholas.lynn@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Kehres, Katherine (CMS/CM)" <katherine.kehres1@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>; "Wojcicki, Michelle (CMS/CM)" <michelle.wojcicki2@cms.hhs.gov>
CC:	"Hess, Matthew (CMS/CM)" <matthew.hess@cms.hhs.gov>
BCC:	
Subject:	RE: RE: CMS Medicare Drug Price Negotiation Program IPAY 2026: CMS Response to Pre-Disclosure Review

Out of Scope

From: Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>
Sent: Monday, December 16, 2024 9:04 AM
To: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>; Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>; Boone, Chanelle (CMS/CM) <Chanelle.Boone@cms.hhs.gov>; Lynn, Nicholas (CMS/CM) <nicholas.lynn@cms.hhs.gov>; Heider, Daniel (CMS/CM) <daniel.heider@cms.hhs.gov>; Rosenberg, Corey (CMS/CM) <Corey.Rosenberg@cms.hhs.gov>; Kehres, Katherine (CMS/CM) <katherine.kehres1@cms.hhs.gov>; Daniel, Elisabeth (CMS/CM) <elisabeth.daniel@cms.hhs.gov>; Garrigan, Thomas (CMS/CM) <thomas.garrigan@cms.hhs.gov>; Wojcicki, Michelle (CMS/CM) <michelle.wojcicki2@cms.hhs.gov>
Cc: Hess, Matthew (CMS/CM) <matthew.hess@cms.hhs.gov>
Subject: FW: CMS Medicare Drug Price Negotiation Program IPAY 2026: CMS Response to Pre-Disclosure Review

Out of Scope

From: timmo.andersen@boehringer-ingelheim.com <timmo.andersen@boehringer-ingelheim.com>
Sent: Friday, December 13, 2024 3:41 PM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Subject: Automatic reply: CMS Medicare Drug Price Negotiation Program IPAY 2026: CMS Response to Pre-Disclosure Review

ï»¿On PTO until end of year where I leave Boehringer.

Will not be checking emails.

For urgent topics call, text or WhatsApp.

Take care,

Timmo

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From:	"Kennedy, Hayden R" <hayden.kennedy@abbvie.com>
Sent:	3/1/2024 2:51:19 PM -0500
To:	"Seshamani, Meena (CMS/OA)" <Meena.Seshamani@cms.hhs.gov>; CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
CC:	"Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>
BCC:	
Subject:	Imbruvica "Counteroffer" Supplemental Letter
Attachments:	image001.gif; Counteroffer Supplement_3.1.24 - signed.pdf

Dr. Seshamani,

Attached please find a cover letter to accompany AbbVie/Pharmacyclics' "counteroffer" response with respect to Imbruvica.

Sincerely,

Hayden Kennedy

HAYDEN R. KENNEDY

Vice President

Global Policy & U.S. Access Strategies
Government Affairs

1 North Waukegan Road

AP34

North Chicago, IL 60064

CELL: (b)(6)

EMAIL hayden.kennedy@abbvie.com

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MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT

(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

Pharmacyclics LLC
(hereinafter referred to as the "Manufacturer")

For

Imbruvica
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program"), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on August 29, 2023; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section

1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—

i. maximum fair price eligible individuals, who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and

ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;

ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and

iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.

f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—

i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service

Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.

g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.
b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.
c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.
b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.
c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.
d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.
e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.
f) In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.
g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations,

or guidance.

j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement.

k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

Date: 09/30/2023

Name: Kevin Buckbee

Title: Senior Vice President

P-Number: P1396

Manufacturer Address: 1 North Waukegan Road, North Chicago, Illinois 60064

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Date: 09/30/2023

Name: Cheri Rice

Title: Deputy Director
Center for Medicare

Signature: ----------

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM

(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

Pharmacyclics LLC
(hereinafter referred to as the "Manufacturer")

For

Imbruvica
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on 09/30/2023, to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [redacted] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.

b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.

c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

Date: 07/02/2024

Name: Michael Staff

Title: VP IRA Channel Strategies

P-Number: P1396

Manufacturer Address: 1 North Waukegan Road, North Chicago, Illinois 60064

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Date:

Name:

Title:

Signature:

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT

(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

Pharmacyclics LLC
(hereinafter referred to as the "Manufacturer")

For

Imbruvica
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program"), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on August 29, 2023; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section

1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—

i. maximum fair price eligible individuals, who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and

ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;

ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and

iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.

f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—

i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service

Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.

g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.
b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.
c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.
b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.
c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.
d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.
e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.
f) In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.
g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations,

or guidance.

j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement.

k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

Date: 09/30/2023

Name: Kevin Buckbee

Title: Senior Vice President

P-Number: P1396

Manufacturer Address: 1 North Waukegan Road, North Chicago, Illinois 60064

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Date: 09/30/2023

Name: Cheri Rice

Title: Deputy Director
Center for Medicare

Signature: ----------

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM

(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

Pharmacyclics LLC
(hereinafter referred to as the "Manufacturer")

For

Imbruvica
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on 09/30/2023, to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [redacted] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.

b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.

c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

Date: 07/02/2024

Name: Michael Staff

Title: VP IRA Channel Strategies

P-Number: P1396

Manufacturer Address: 1 North Waukegan Road, North Chicago, Illinois 60064

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Date:

Name:

Title:

Signature:

Salix Pharmaceuticals

BAUSCH Health

400 Somerset Corporate Boulevard
Bridgewater, New Jersey 08807

908 927 1400
bauschhealth.com

Submitted electronically

December 20, 2024

Centers for Medicare & Medicaid Services
CMS Medicare Drug Rebate and Negotiations Group

To Whom It May Concern,

This letter is being submitted in accordance with the guidance in the email received from the CMS Medicare Drug Rebate and Negotiations Group at 10:03PM on Thursday, December 19, 2024.

I confirm that I am a Director of Salix Pharmaceuticals, Inc., as well as its Senior Vice President, Controller, and Chief Accounting Officer. As such, my position meets the requirements in the SBE Instructions that the certification of the SBE Request may be made by "an individual other than a CEO or CFO, who has authority equivalent to a CEO or CFO of the Submitting Manufacturer." My CMS User ID in HPMS is "BEUA".

Accordingly, we are also resubmitting the accepted SBE Request sent on December 18, 2024 for reference, which has been certified by me.

Please contact me should you have any questions or if you would like to discuss further.

Respectfully,

John S. Barresi
Senior Vice President, Controller, and Chief Accounting Officer
Salix Pharmaceuticals Inc.

AstraZeneca AB
SE-151 85 Södertälje, Sweden
T: +46 8 553 260 00
F: +46 8 553 290 00
astrazeneca.com

Medicare Drug Rebate and Negotiation Group
IRARebateandNegotiation@cms.hhs.gov

To Whom It May Concern:

AstraZeneca AB hereby requests that Emery Melville, Director Government Reporting, CMS User ID MIA5; and Rodrigue Lauzon, Executive Director, Contract Operations, CMS User ID LFFD be granted electronic signature access for the following P number(s): P1174, P1137.

Emery Melville, Director of Government Reporting, and Rodrigue Lauzon, Executive Director Contract Operations, are hereby granted authority to act for and on behalf of AstraZeneca AB solely in connection with such P number(s), including the authority to execute any such documents on behalf of AstraZeneca AB in connection with such P numbers.

For and on behalf of
AstraZeneca AB (publ)

Digitally signed by Lars-Johan Cederbrant
Date: 2023.09.26 13:56:13 +02'00'

Lars-Johan Cederbrant
CFO, AstraZeneca AB

Date: 26-Sep-2023

From:	"Roche, Jacqueline [JJCUS]" <jroche8@its.jnj.com>
Sent:	6/27/2024 3:15:11 PM -0400
To:	"Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC:	"McNamara, Stefanie [JJCUS]" <SMcNama7@its.jnj.com>; "Hancock, Rebecca [JJCUS]" <RHancoc1@ITS.JNJ.com>; "Schaeffer, John [HCSUS]" <JSchaeff@ITS.JNJ.com>; "Teeple, Amanda [JRDUS]" <ateeple@ITS.JNJ.com>
BCC:	
Subject:	MFP Effectuation Memo_ CMS Authority
Attachments:	Final MFP Effectuation Memo.pdf

Hi, Kristi and Chris: Attached is a memo prepared for J&J and CMS regarding CMS' authority in establishing an effectuation model that includes a pre-fund. I'm also introducing my J&J GC colleague, Stefanie McNamara.

Help me with the CMS preferred timing to discuss and/or if it would be helpful for us to send this memo directly to OGC.

We are available to discuss and walk both the CMS and HHS/OGC teams through the memo.

Thank you,

Jackie & Stefanie

Kind Regards,

Jacqueline Roche

Head Payment and Delivery & Global Policy Institute

Johnson & Johnson Worldwide Government Affairs & Policy WWGA&P

Mobile: (b)(6)

Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

From:	"Roche, Jacqueline [JJCUS]" <jroche8@its.jnj.com>
Sent:	6/27/2024 3:15:11 PM -0400
To:	"Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC:	"McNamara, Stefanie [JJCUS]" <SMcNama7@its.jnj.com>; "Hancock, Rebecca [JJCUS]" <RHancoc1@ITS.JNJ.com>; "Schaeffer, John [HCSUS]" <JSchaeff@ITS.JNJ.com>; "Teeple, Amanda [JRDUS]" <ateeple@ITS.JNJ.com>
BCC:	
Subject:	MFP Effectuation Memo_ CMS Authority
Attachments:	Final MFP Effectuation Memo.pdf

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Thank you,

Jackie & Stefanie

Kind Regards,

Jacqueline Roche

Head Payment and Delivery & Global Policy Institute

Johnson & Johnson Worldwide Government Affairs & Policy WWGA&P

Mobile: (b)(6)

Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

From:	"Cirri, Liz /US" <Liz.Cirri@sanofi.com>
Sent:	7/26/2023 11:22:51 AM -0400
To:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>
CC:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
BCC:	
Subject:	Sanofi IRA 2026 Medicare QSSD Drug Selection - Glargine
Attachments:	image001.png; image002.png; image003.png; image004.png; image005.png; image006.png; Sanofi - CMS IRA QSSD.pdf

Dear CMS Leadership Lara Strawbridge and Kristi Martin,

As CMS works to select qualifying single sources drugs for the initial price applicability year 2026 for Medicare negotiation under the Inflation Reduction Act, please find attached a letter from Sanofi with some pertinent information regarding Lantus (insulin glargine). Please reach out with any questions.

Thank you in advance for your consideration and review of this information.

Best Regards,

Liz Cirri

Head, US Reimbursement and Public Policy

US Corporate Affairs

Cell: (b)(6)

Liz.Cirri@sanofi.com

55 Corporate Drive, Bridgewater, NJ 08807

I use our flexible work policy to help me balance my responsibilities to my job and my family and may send emails outside of normal working hours. Please do not feel the need to read or respond to this email outside of your working hours.

From:	"Cirri, Liz /US" <Liz.Cirri@sanofi.com>
Sent:	7/26/2023 11:22:51 AM -0400
To:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>
CC:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
BCC:	
Subject:	Sanofi IRA 2026 Medicare QSSD Drug Selection - Glargine
Attachments:	image001.png; image002.png; image003.png; image004.png; image005.png; image006.png; Sanofi - CMS IRA QSSD.pdf

Dear CMS Leadership Lara Strawbridge and Kristi Martin,

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Thank you in advance for your consideration and review of this information.

Best Regards,

Liz Cirri

Head, US Reimbursement and Public Policy

US Corporate Affairs

Cell: (b)(6)

Liz.Cirri@sanofi.com

55 Corporate Drive, Bridgewater, NJ 08807

I use our flexible work policy to help me balance my responsibilities to my job and my family and may send emails outside of normal working hours. Please do not feel the need to read or respond to this email outside of your working hours.

MODEL TABLE 4. Per Patient Per Month (PPPM) costs and Per Patient Per Year (PPPY) Total Cost Overview per Comparator and for Key Discount Rates, 1-Year Time Horizon

COMPARATORS	Treatment Naïve CLL		Relapsed & Refractory CLL	
	PPPM	PPPY	PPPM	PPPY
Acalabrutinib	$15,081	$180,974	$15,949	$191,384
Zanubrutinib	$15,038	$180,459	$15,191	$182,290
Ibrutinib (-10%)	$15,760	$189,114	$16,427	$197,123
Ibrutinib (-15%)	**$14,948**	**$179,375**	$15,604	$187,252
Ibrutinib (-18%)	$14,461	$173,532	**$15,111**	**$181,329**
Ibrutinib (-20%)	$14,136	$169,636	$14,782	$177,381

Note: Bold indicates Ibrutinib 2023 WAC discount rate necessary for ibrutinib to be cost-minimizing relative to therapeutic alternatives.

Best Price (BP) Standard Refile					
Selected Drug Name	NDC-9	Quarter	Medicaid Best Price ($) ICR Submission	Medicaid Best Price ($) Refile [1]	Unit Type
STELARA	578940054	Q1 2021	$ 47.59	$ 42.66	ML
STELARA	578940060	Q1 2021	$ 9,415.40	$ 9,095.38	ML
STELARA	578940061	Q1 2021	$ 9,415.40	$ 9,577.27	ML
XARELTO	504580577	Q1 2021	$ 3.09	$ 3.13	TAB
XARELTO	504580578	Q1 2021	$ 6.17	$ 6.27	TAB
XARELTO	504580579	Q1 2021	$ 6.17	$ 6.27	TAB
XARELTO	504580580	Q1 2021	$ 6.17	$ 6.27	TAB
XARELTO	504580584	Q1 2021	$ 6.17	$ 6.27	TAB
Notes:					

1. In the normal course of business and as required under the Medicaid Drug Rebate Program, manufacturers must report any revised Best Price within twelve quarters timeframe*. The revised Best Price incorporates the final discounts realized that were previously estimated in the initial Best Price filing for each quarter.

*42 C.F.R. § 447.510(b)(1)

Best Price (BP) Standard Refile					
Selected Drug Name	NDC-9	Quarter	Medicaid Best Price ($) ICR Submission	Medicaid Best Price ($) Refile [1]	Unit Type
STELARA	578940054	Q1 2021	$ 47.59	$ 42.66	ML
STELARA	578940060	Q1 2021	$ 9,415.40	$ 9,095.38	ML
STELARA	578940061	Q1 2021	$ 9,415.40	$ 9,577.27	ML
XARELTO	504580577	Q1 2021	$ 3.09	$ 3.13	TAB
XARELTO	504580578	Q1 2021	$ 6.17	$ 6.27	TAB
XARELTO	504580579	Q1 2021	$ 6.17	$ 6.27	TAB
XARELTO	504580580	Q1 2021	$ 6.17	$ 6.27	TAB
XARELTO	504580584	Q1 2021	$ 6.17	$ 6.27	TAB
Notes:					

1. In the normal course of business and as required under the Medicaid Drug Rebate Program, manufacturers must report any revised Best Price within twelve quarters timeframe*. The revised Best Price incorporates the final discounts realized that were previously estimated in the initial Best Price filing for each quarter.

*42 C.F.R. § 447.510(b)(1)

From:	"Hunter, Kaitlin (CMS/CM)" <Kaitlin.Hunter@cms.hhs.gov>
Sent:	12/19/2024 12:28:27 PM -0500
To:	"Tucker, Caroline" <Caroline.Tucker@bms.com>; "Weiss, Rachel (CMS/CM)" <rachel.weiss@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Coster, John (CMS/CM)" <John.Coster@cms.hhs.gov>; "Li, Tina (CMS/CM)" <ting.li@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>
CC:	"Verb, Katie" <Katie.Verb@bms.com>; "Knott, William" <William.Knott@bms.com>
BCC:	
Subject:	RE: RE: BMS: Requested Follow-up from 12/10 Meeting
Attachments:	image001.png

Hi Caroline and team,

Thanks for sending—we appreciate the follow-up! We'll take a look at what you've shared and be in touch if we have any questions.

Happy holidays!

Best,

Kaitlin

From: Tucker, Caroline <Caroline.Tucker@bms.com>
Sent: Wednesday, December 18, 2024 12:32 PM
To: Weiss, Rachel (CMS/CM) <rachel.weiss@cms.hhs.gov>; Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>; Coster, John (CMS/CM) <John.Coster@cms.hhs.gov>; Li, Tina (CMS/CM) <ting.li@cms.hhs.gov>; Hunter, Kaitlin (CMS/CM) <Kaitlin.Hunter@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>
Cc: Verb, Katie <Katie.Verb@bms.com>; Knott, William <William.Knott@bms.com>
Subject: BMS: Requested Follow-up from 12/10 Meeting

FOIA EXEMPT – CONFIDENTIAL INFORMATION – NOT FOR PUBLIC DISCLOSURE

Hi all, please find the requested follow-up from our meeting last week below. I'm sharing with those on the calendar invite, but please share with others on the call we might have missed.

Thank you for meeting with us on December 10 to discuss the policy and market access reasons why our drug Pomalyst should not be selected during the IPAY 2027 selection process. As discussed, Pomalyst is a convenient, oral standard of care immunomodulatory drug (IMiD) used in the treatment of relapsed refractory multiple myeloma (RRMM) and Kaposi Sarcoma (KS). Based on both confidential internal and public external assessments, Pomalyst is expected to lose exclusivity in Q1 2026, with six generic products expected to enter the market in Q1 2026 and nine generic products expected to enter the market by the end of 2026. The number of generic competitors points to significant anticipated market erosion. It is likely that plans will prioritize generics over Pomalyst through utilization management, and branded Pomalyst will potentially be removed from formulary altogether in 2H 2026. We believe CMS will not benefit from Pomalyst's selection over true single source, high-expenditure products due to the rapid market erosion and shift to generic alternatives.

In our meeting, you requested our thoughts on legal authority to make such a determination in your selection process. We note first that under Subsections 1192(d)(1) and 1192(b)(1), the process entails (1) a determination that a drug is "among the 50 qualifying single source drugs [QSSDs] with the highest total expenditures" under Medicare Part D; (2) a ranking of the 50 highest expenditure drugs "as determined by the Secretary"; and then (3) selection of highest-ranking drugs "from" that ranking. This text provides the Agency with discretion in selection; it can choose to select one of the highest ranked drugs other than Pomalyst in this round. Were it otherwise, then the provision requiring a determination that a drug is among the 50 QSSDs and the overarching ranking of many more drugs than the 15 that must be selected would appear superfluous. Additionally, the provision of a "selection" process itself suggests that CMS has some measure of discretion to pick from the list of negotiation-eligible drugs. The plain meaning of the word "select" implies judgment, rather than a rote counting exercise. The definition of a "selected drug" emphasizes the Secretary's (and by extension CMS') role in determining the ranking ("as determined by the Secretary"), indicating a degree of discretion.

Further, when the innovator product will face generic competition before the IPAY begins, CMS can exercise its discretion to make a determination that the product is ineligible for selection due to the generic competition. Here, before January 1, 2027, Pomalyst will no longer meet the definition of a QSSD, a necessary predicate to meeting the definition of a negotiation-eligible drug and a selected drug, before the first day of IPAY 2027. Section 1192(e)(1)(A)(iii) provides that a drug is not a QSSD upon marketing of a generic drug for which it is the listed drug under section 505(j) of the FDCA, without imposing a time limitation on this condition. This, along with language defining a QSSD "with respect to an [IPAY]" indicates that Congress contemplated that CMS could consider whether a drug will still meet the definition of a QSSD on the first day of the IPAY.

The provisions above all support the Secretary using appropriate judgment in the selection process to choose the drugs that will best fulfill the statute's purpose. Further, CMS' selection decision is not subject to judicial review. Selecting Pomalyst would reduce CMS' opportunity to promote overall greater cost savings for the Medicare program and patients. Given the circumstances of Pomalyst as likely subject to generic competition before an MFP goes into effect on January 1, 2027, CMS should exercise discretion in the selection of products and not choose Pomalyst for IPAY 2027.

We hope these thoughts are helpful and appreciate your time and consideration.

Thank you and happy holidays!!!

Caroline & the BMS Team

Caroline P. Tucker

Director | Executive Branch Strategy

US Policy & Government Affairs

Email: caroline.tucker@bms.com

Mobile: (b)(6)

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Immunex Corporation
One Amgen Center Drive
Thousand Oaks, CA 91320

November 4, 2024

Submitted Via CMS Box.com Folder

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Opportunity for Pre-Disclosure Review of Manufacturer-Submitted Materials to Accompany Publication of Maximum Fair Price Explanation

To Whom It May Concern,

Immunex has serious concerns with the approach to disclosing proprietary information described in CMS's October 18, 2024 letter to Immunex.

The agency's position violates the Inflation Reduction Act ("IRA"). Under section 1193(c) of the Social Security Act (the Act), in a provision added by the IRA, "[i]nformation submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part." The language chosen by Congress as triggering confidential treatment—"proprietary information"—is readily distinguishable from that used in FOIA Exemption 4 (which governs "trade secrets and commercial or financial information" that is "privileged or confidential").

In any event, Immunex's information readily satisfies the requirements of FOIA Exemption 4, which protects information "whenever it is customarily kept private, or at least closely held, by the person imparting it." *Food Marketing Institute v. Argus Leader Media*, 588 U.S. 427, 434 (2019). There is no separate requirement that submitters *also* must demonstrate that they provided the information pursuant to assurance of confidentiality. *Id.; see also Naumes v. Dep't of the Army*, 588 F. Supp. 3d 23, 40 (D.D.C. 2022). Nonetheless, Immunex submitted the disputed information with a reasonable expectation of confidentiality. Most importantly, the IRA itself provides an assurance of confidentiality by protecting proprietary information from disclosure. Moreover, the information at issue is of the type routinely treated as confidential by CMS. Accordingly, the entire mandatory submission of Immunex under section 1194(e)(1) of the Act should be treated as proprietary.

Despite our concerns with CMS's misguided interpretation of the IRA, we have uploaded an edited version of the "Section 1194(e)(1) Data Factors" document that CMS provided. We have highlighted in green the additional information that would qualify as protected from disclosure under the standards articulated in the October 18 letter.

We summarize below why the information highlighted in green meets the standards of the October 18 letter.

C. Research and Development Cost

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** Immunex does not maintain research and development cost information in the usual course of business in the format requested in Information Collection Request Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (the "IRA ICR") and it was necessary for Immunex to prepare data for this submission relying on certain assumptions. The highlighted explanatory notes lay out the assumptions Immunex relied on in preparing its submission. This information has been kept close hold within Immunex.
- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the June 30, 2023 "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026" (the "IPAY 2026 Guidance"), CMS states that "research and development costs and recoupment" information will be treated as proprietary.

D. Current Unit Costs of Production and Distribution

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** Immunex does not maintain cost information in the usual course of business in the format requested in the IRA ICR and it was necessary for Immunex to prepare data for this submission relying on certain assumptions. The highlighted explanatory notes lay out the assumptions Immunex relied on in preparing its submission. This information has been kept close hold within Immunex. The information regarding sales of specific NDCs is not public. We also highlighted information that summarizes confidential communications between Immunex and FDA.
- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the IPAY 2026 Guidance, CMS states that "unit costs of production and distribution" information will be treated as proprietary.

G. Market Data and Revenue and Sales Volume Data, Wholesale Acquisition Cost Unit Price

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** The explanatory notes summarize assumptions Immunex made in preparing its submission. This information has been kept close hold within Immunex. The information regarding WAC data of specific NDCs is not public. We also highlighted information that summarizes confidential communications between Immunex and FDA.
- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the IPAY 2026 Guidance, CMS states that "market data, revenue, and sales volume data" information will be treated as proprietary.

G. Market Data and Revenue and Sales Volume Data, Medicaid Best Price

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** Immunex's reasonable assumptions are sensitive business information that would be of value to competitors. The explanations regarding Best Price data of specific NDCs are not public. We also highlighted information that summarizes confidential communications between Immunex and FDA.
- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the IPAY 2026 Guidance, CMS states that "market data, revenue, and sales volume data" information will be treated as proprietary.

G. Market Data and Revenue and Sales Volume Data, Federal Supply Schedule Price

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** The explanatory notes summarize assumptions Immunex made in preparing its submission. This information has been kept close hold within Immunex. The information regarding sales of specific NDCs is not public. We also highlighted information that summarizes confidential communications between Immunex and FDA.
- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the IPAY 2026 Guidance, CMS states that "market data, revenue, and sales volume data" information will be treated as proprietary.

G. Market Data and Revenue and Sales Volume Data, Big Four Price

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** The explanatory notes summarize assumptions Immunex made in preparing its submission. This information has been kept close hold within Immunex. The information regarding sales of specific NDCs is not public. We also highlighted information that summarizes confidential communications between Immunex and FDA.
- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the IPAY 2026 Guidance, CMS states that "market data, revenue, and sales volume data" information will be treated as proprietary.

G. Market Data and Revenue and Sales Volume Data, U.S. Commercial Average Net Unit Price

- **FOIA Exemption:** 4.
- **Whether Kept Private or Close Hold:** The explanatory notes summarize assumptions Immunex made in preparing its submission. This information has been kept close hold

within Immunex. The information regarding sales of specific NDCs is not public. We also highlighted information that summarizes confidential communications between Immunex and FDA.

- **Assurance of Confidentiality:** The IRA provides an assurance of confidentiality by protecting proprietary information from disclosure. *See* 42 U.S.C. § 1320f-2(c). Under section 40.2.1 of the IPAY 2026 Guidance, CMS states that "market data, revenue, and sales volume data" information will be treated as proprietary.

Immunex requests that the information we have highlighted in green be kept confidential. If CMS concludes otherwise, we request prompt notification of the agency's permission so that Immunex may take steps to protect its interests. *See, e.g.*, 45 C.F.R. 5.42(a).

Sincerely,

Yola Gawlik

Yola Gawlik
Executive Director, Health Policy & Reimbursement
Immunex Corporation

Appointment Title:	External Call: Amgen
Organizer:	Martin, Kristi (CMS/CM)
Attendees:	Jennifer Young <jyoung@tdyllc.com>; Rice, Cheri (CMS/CM); Ahern, Robert (CMS/CM); Hutchinson, Claire (CMS/CM); Ritter, Christina (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Coster, John (CMS/CM); Daniel, Elisabeth (CMS/CM); Garrigan, Thomas (CMS/CM); Lang, Kelsey; Yip, Rebecca (CMS/CM); Eschliman, Brede (CMS/CM); Healy, Vicki; Pettit, Chad; Wojcicki, Michelle (CMS/CM); Linder, Max (CMS/CM); Selde, Steven (CMS/CM)
Location:	https://cms.zoomgov.com/ (b)(6) pwd (b)(6)
Start Time:	6/4/2024 3:30:00 PM -0400
End Time:	6/4/2024 4:00:00 PM -0400
Reminder Time:	6/4/2024 3:15:00 PM -0400
Reminder Set:	false
Duration:	30 minutes
Is Recurring:	false
Reccurrance Pattern:	
Response Status:	3
Busy Status:	Busy
Attachments:	Meeting Request Form IRA Biosimilar Discussion (Final May 15 2024).doc; Biosimilar Delay CMS 20240531 FINAL.pdf

Amgen would like to discuss considerations for implementing the Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry provision of the IRA for future IPAYs, including â€"

- Information available to manufacturers
- Request deadlines
- Standards for â€œhigh likelihoodâ€□ and â€œsignificant progressâ€□

Demonstration of bona fide marketing

CARIE Spangler is inviting you to a scheduled ZoomGov meeting.

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Dial by your location

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This meeting may be recorded. The host is responsible for maintaining any official recordings/transcripts of this meeting. If recorded, this meeting becomes an official record and shall be retained by the host in their files for 3 years or if longer needed for agency business. If a recording intends be fully transcribed or is being captured for the purpose of creating meeting minutes, the host shall retain the record in their files for 3 years or if no longer needed for agency business, whichever is later.

Page 86 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
(b)(5)

From:	"Seshamani, Meena (CMS/OA)" <Meena.Seshamani@cms.hhs.gov>
Sent:	12/9/2024 8:13:27 PM -0500
To:	"Shiraki, Matt" <matt.shiraki@abbvie.com>; "Blum, Jonathan (CMS/OA)" <Jonathan.Blum@cms.hhs.gov>
CC:	"Kennedy, Hayden R" <hayden.kennedy@abbvie.com>; "Shiraki, Matt" <matt.shiraki@abbvie.com>
BCC:	
Subject:	Re: Re: AbbVie Letter to CMS (Ineligibility of CREON for IRA IPAY 2027)
Attachments:	image001.gif

Thank you, received.

Get Outlook for iOS

From: Shiraki, Matt <matt.shiraki@abbvie.com>
Sent: Monday, December 9, 2024 7:05:24 PM
To: Blum, Jonathan (CMS/OA) <Jonathan.Blum@cms.hhs.gov>; Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>
Cc: Kennedy, Hayden R <hayden.kennedy@abbvie.com>; Shiraki, Matt <matt.shiraki@abbvie.com>
Subject: AbbVie Letter to CMS (Ineligibility of CREON for IRA IPAY 2027)

Dear Principal Deputy Administrator Blum and Dr. Seshamani:

On behalf of Hayden Kennedy (Vice President, Global Policy & U.S. Access Strategies, Government Affairs, AbbVie), I have attached AbbVieâ€™s letter to CMS regarding ineligibility of CREON for IRA IPAY 2027. Please confirm receipt.

Thank you for reviewing our letter, and please let me know if you have any questions.

Best,
Matt

MATT SHIRAKI
Director, Therapeutic Area Strategies (Oncology & Specialty)
Government Affairs

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Subject: Update– MFP Application Across Dosage Forms and Strengths for IPAY 2026

Dear Pharmacyclics LLC,

In accordance with section 1194(c) of the Social Security Act ("the Act") and section 60.2 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("Revised Guidance"), CMS calculated the ceiling for Imbruvica. Further, in accordance with section 1196(a)(2) of the Act and section 60.5 of the Revised Guidance, CMS calculated how any agreed-upon maximum fair price (MFP) would apply across dosage forms and strengths of Imbruvica. On December 1st, 2023, CMS sent an email to Pharmacyclics LLC, Inc. with a link to the results of these calculations for Imbruvica and a suggestion of error form. The email was sent from the (IRARebateandNegotiation@cms.hhs.gov) email box to ADD NAMES.

CMS has updated the document that details how any agreed-upon MFP would apply across dosage forms and strengths of Imbruvica. CMS has deleted two sample package NDC-11s (57962-0420-71 and 57962-0560-71) from the "MFP NDC Calculator" worksheet in the "Manu_MFP_DFS_IPAY2026_Imbruvica_041524.xlsx" Excel file; any agreed upon MFPs would not apply to these two sample NDC-11s. The updated "Manu_MFP_DFS_IPAY2026_Imbruvica_041524.xlsx" Excel file has been uploaded to Box (ADD LINK) and is ready for download. If you are unable to access the link to the revised document, please respond to this email to let us know how you would like to receive them.

As described in section 40.2 of the Revised Guidance, of the Primary Manufacturer has an ongoing obligation to timely report any changes to the list of NDC-11s of the selected drug to ensure the list of NDC-11s remains complete and accurate.

Thank you,
CMS Medicare Drug Rebate and Negotiations Group

Subject: Update– MFP Application Across Dosage Forms and Strengths for IPAY 2026

Dear Janssen Biotech, Inc.,

In accordance with section 1194(c) of the Social Security Act ("the Act") and section 60.2 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("Revised Guidance"), CMS calculated the ceiling for Stelara. Further, in accordance with section 1196(a)(2) of the Act and section 60.5 of the Revised Guidance, CMS calculated how any agreed-upon maximum fair price (MFP) would apply across dosage forms and strengths of Stelara. On December 1st, 2023, CMS sent an email to Janssen Biotech, Inc. with a link to the results of these calculations for Stelara and a suggestion of error form. The email was sent from the (IRARebateandNegotiation@cms.hhs.gov) email box to ADD NAMES.

CMS has updated the document that details how any agreed upon MFP would apply across dosage forms and strengths of Stelara. CMS has deleted three sample package NDC-11s (57894-0054-16, 57894-0060-04, 57894-0061-04) from the "MFP NDC Calculator" worksheet in the "Manu_MFP_DFS_IPAY2026_Stelara_041524.xlsx" Excel file; any agreed upon MFP would not apply to these three sample package NDC-11s. The updated "Manu_MFP_DFS_IPAY2026_Stelara_041524.xlsx" Excel file has been uploaded to Box (ADD LINK) and is ready for download. If you are unable to access the link to the revised document, please respond to this email to let us know how you would like to receive them.

As described in section 40.2 of the Revised Guidance, the Primary Manufacturer has an ongoing obligation to timely report any changes to the list of NDC-11s of the selected drug to ensure the list of NDC-11s remains complete and accurate.

Thank you,
CMS Medicare Drug Rebate and Negotiations Group

Medicare Drug Price Negotiation Program – MFP Counteroffer for Jardiance

MB Marsh,Christine (HP MA) BIP-US-R <christine.marsh@boehringer-ingelheim.com>

Reply all

Today, 3:35 PM
CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>; E+2 more

Encrypt: This message is encrypted. Recipients can't remove encryption.

This message has been marked as Confidential.

Dear Medicare Drug Rebate and Negotiation Group,

Today, Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") in response to CMS's initial "maximum fair price" determination for BI's Jardiance® medications, submitted our counteroffer into HPMS.

BI submitted this information under continued protest. As stated in its cover letter accompanying the "Medicare Drug Price Negotiation Agreement," BI has been forced to participate in the Drug Price Negotiation Program by the terms of the Inflation Reduction Act. Now that CMS has made an initial price determination, the Act limits BI to either accepting CMS's price or "propos[ing] a counteroffer." BI has taken the latter approach because, as alleged in BI's Complaint in Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS, No. 3:23-cv-01103 (D. Conn.), BI does not consider CMS's price to be "fair," nor the product of a true "negotiation." Accordingly, the submitted counteroffer should not be construed as implying acquiescence to the Drug Price Negotiation Program, or agreement with the resulting "maximum fair price." Instead, BI reserves all its rights with respect to the Program, including the legal claims presented in its Complaint.

Information submitted by BI into the HPMS system includes trade secret and confidential commercial information and is exempt from public disclosure under 5 U.S.C. § 552(b)(4).

Sincerely,

Christine Marsh
SVP, Value & Access

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road | Ridgefield CT 06877

T +1 (203) 798-4780
M (b)(6)
E christine.marsh@boehringer-ingelheim.com

Life forward

From:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>
Sent:	9/5/2024 2:44:24 PM -0400
To:	"Hess, Matthew (CMS/CM)" <matthew.hess@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC:	"Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>
BCC:	
Subject:	RE: RE: MDPNP Comment Publication
Attachments:	Medicare Drug Price Negotiation Program Public Submissions_8.26.2024_LS.pdf

Out of Scope

From: Strawbridge (she/her), Lara (CMS/CM)
Sent: Tuesday, August 27, 2024 1:17 PM
To: Hess, Matthew (CMS/CM) <matthew.hess@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Cc: Daniel, Elisabeth (CMS/CM) <elisabeth.daniel@cms.hhs.gov>
Subject: RE: MDPNP Comment Publication

Out of Scope

From: Hess, Matthew (CMS/CM) <matthew.hess@cms.hhs.gov>
Sent: Tuesday, August 27, 2024 1:14 PM
To: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Cc: Daniel, Elisabeth (CMS/CM) <elisabeth.daniel@cms.hhs.gov>
Subject: MDPNP Comment Publication

Out of Scope

Out of Scope

From: "Kane, Corden (CMS/CM)" <corden.kane2@cms.hhs.gov>
Sent: 12/16/2024 9:04:27 AM -0500
To: "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Boone, Chanelle (CMS/CM)" <Chanelle.Boone@cms.hhs.gov>; "Lynn, Nicholas (CMS/CM)" <nicholas.lynn@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Kehres, Katherine (CMS/CM)" <katherine.kehres1@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>; "Wojcicki, Michelle (CMS/CM)" <michelle.wojcicki2@cms.hhs.gov>
CC: "Hess, Matthew (CMS/CM)" <matthew.hess@cms.hhs.gov>
BCC:
Subject: FW: FW: CMS Medicare Drug Price Negotiation Program IPAY 2026: CMS Response to Pre-Disclosure Review

Out of Scope

From: timmo.andersen@boehringer-ingelheim.com <timmo.andersen@boehringer-ingelheim.com>
Sent: Friday, December 13, 2024 3:41 PM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Subject: Automatic reply: CMS Medicare Drug Price Negotiation Program IPAY 2026: CMS Response to Pre-Disclosure Review

ï»¿On PTO until end of year where I leave Boehringer.

Will not be checking emails.

For urgent topics call, text or WhatsApp.

Take care,

Timmo

This e-mail is confidential and may also be legally privileged. If you are not the intended recipient please reply to sender, delete the e-mail and do not disclose its contents to any person. Any unauthorized review, use, disclosure, copying or distribution is strictly prohibited.

Subject: Updated MFP Application Across Dosage Forms and Strengths for IPAY 2026

Dear Novartis Pharms Corp,

In accordance with section 1196(a)(2) of the Social Security Act (the Act) and section 60.5 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("revised guidance"), CMS has updated its computation of how any agreed-upon maximum fair price (MFP) will apply across dosage forms and strengths of Entresto based on the identification of new National Drug Code (NDC)-11s for Entresto.

As described in section 40.5 of the revised guidance, CMS developed the interactive tool for Novartis Pharms Corp that demonstrates how CMS will apply the negotiated MFP across dosage forms and strengths of Entresto. Given that CMS has updated its computation to incorporate new NDCs as indicated in your response to CMS' email dated June 14, as described in section 40.5 of the revised guidance, a Primary Manufacturer who believes in good faith that CMS has made an error in the computation of how CMS will apply the single MFP across dosage forms and strengths may submit a suggestion of error for CMS' consideration. A Primary Manufacturer has 30 days to submit a suggestion of error and may do so by submitting the request via email to this email box (IRARebateandNegotiation@cms.hhs.gov) with the subject line "Suggestion of Error for Entresto." CMS will review and respond within 30 days of receiving the suggestion of error from the Primary Manufacturer if feasible.

Please find this updated interactive tool for Entresto available for download in Box [add Box link]. If you are unable to access the link to the interactive tool, please respond to this email to let us know how you would like to receive it.

Thank you,

CMS Medicare Drug Rebate and Negotiations Group

From:	"Kane, Corden (CMS/CM)" <corden.kane2@cms.hhs.gov>
Sent:	10/28/2024 12:04:54 PM -0400
To:	"Hess, Matthew (CMS/CM)" <matthew.hess@cms.hhs.gov>; "Boone, Chanelle (CMS/CM)" <Chanelle.Boone@cms.hhs.gov>; "Wojcicki, Michelle (CMS/CM)" <michelle.wojcicki2@cms.hhs.gov>
CC:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Lynn, Nicholas (CMS/CM)" <nicholas.lynn@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Kehres, Katherine (CMS/CM)" <katherine.kehres1@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>
BCC:	
Subject:	RE: RE: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box

Out of Scope

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Monday, October 28, 2024 11:56 AM
To: Boone, Chanelle (CMS/CM) <Chanelle.Boone@cms.hhs.gov>; Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>; Wojcicki, Michelle (CMS/CM) <michelle.wojcicki2@cms.hhs.gov>
Subject: FW: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box

Out of Scope

From: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>
Sent: Monday, October 28, 2024 8:05 AM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Subject: RE: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box

Good morning CMS,

I am just confirming that 10 business days for our response will be this Friday November 1, 2024. Please also advise if identification of FOIA exemptions apply to presentation documents shared by us during the 3 in-person negotiation meeting with CMS.

Regards,

John Schaeffer

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Friday, October 18, 2024 2:09 PM
To: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>; Gemma, Matthew [HCSUS] <MGemma1@its.jnj.com>; Abdullah, Jamillah [HCS] <JAbdulla@its.jnj.com>
Subject: [EXTERNAL] [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box
Importance: High

Dear Janssen Pharmaceuticals, Inc., â€¯

CMS is providing an opportunity for pre-disclosure review of manufacturer-submitted materials. Please see the attached letter for details and instructions.

The individuals representing Janssen Pharmaceuticals, Inc. who currently have access to the CMS Box folder located at (b)(6) for Xarelto, should receive a notification today from noreply@box.com that contains a link to materials CMS has added to your CMS Box folder, within the folder titled â€œPre-Disclosure Reviewâ€□, for your **immediate** review.

To request access for additional individuals or to request removal of access for any individuals to the Box folder, please respond to this email with their names and email addresses, and CMS will share with them a Box access invitation or remove Box access, as appropriate.â€¯â€¯

Sincerely,â€¯

Medicare Drug Rebate and Negotiations Groupâ€¯

JON TESTER
MONTANA

COMMITTEES:
APPROPRIATIONS
BANKING
COMMERCE
INDIAN AFFAIRS
VETERANS' AFFAIRS

United States Senate

SENATE HART BUILDING
SUITE 311
WASHINGTON, DC 20510
202 224 2644

tester.senate.gov/contact

July 3, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Dear Administrator Brooks-LaSure:

As the Center for Medicare and Medicaid Services (CMS) works to implement provisions of the *Inflation Reduction Act* (IRA) Medicare Drug Price Negotiation program, I ask that CMS ensure that plans and pharmacy benefit managers (PBMs) do not charge direct and indirect remuneration (DIR) fees to community pharmacies for negotiated drugs.

Across the U.S., more than 7,000 pharmacies have closed since 2019, and the majority of those pharmacies were independent drugstores. Over 300 independent pharmacies closed their doors in 2023 alone. These closures have hit rural America particularly hard, where a pharmacy closure can mean residents lose access to their only source for local access to vital medications and routine health care. The purpose of the Medicare Drug Price Negotiation was not to cut into the already small margins of community pharmacies. In fact, the IRA is clear that pharmacies are not to be reimbursed below the "maximum fair price" (MFP) for negotiated drugs.

The IRA created an exception to non-interference in the Part D clause in the *Social Security Act*. CMS should use this exception to put guardrails in place to make sure that pharmacies are not reimbursed below the maximum fair price for negotiated drugs. Specifically, I ask that CMS establish a price structure for the Medicare Drug Price Negotiation Program to ensure that pharmacy reimbursement is reasonable and covers acquisition cost, margin, and a commensurate professional dispensing fee. Additionally, please ensure that PBMs cannot assess pharmacy DIR fees on negotiated drugs.

Thank you for the opportunity to provide feedback. I stand ready to work with you on lowering drug costs for seniors in a way that also protects their ability to fill their prescriptions at their local pharmacy.

Sincerely,

Jon Tester

BILLINGS (406) 252-0550 | BOZEMAN (406) 586-4450 | BUTTE (406) 723-3277 | MISSOULA (406) 728-3003 | GREAT FALLS (406) 452-9585 | HELENA (406) 449-5401 | KALISPELL (406) 257-3360

Subject: Update– MFP Application Across Dosage Forms and Strengths for IPAY 2026

Dear Novo Nordisk Inc.,

In accordance with section 1194(c) of the Social Security Act ("the Act") and section 60.2 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("Revised Guidance"), CMS calculated the ceiling for NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; Fiasp PenFill ("NovoLog/Fiasp"). Further, in accordance with section 1196(a)(2) of the Act and section 60.5 of the Revised Guidance, CMS calculated how any agreed-upon maximum fair price (MFP) would apply across dosage forms and strengths of NovoLog/Fiasp. The results of the original ceiling and application of the MFP across dosage forms and strengths calculations were sent to Novo Nordisk Inc. on December 28, 2023. On January 31, 2024, CMS sent an email to Novo Nordisk Inc. with a link to an updated file that details how any agreed upon MFP would apply across dosage forms and strengths of NovoLog/Fiasp. Both emails were sent from the (IRARebateandNegotiation@cms.hhs.gov) email box to ADD NAMES.

CMS has further updated the file that details how any agreed-upon MFP would apply across dosage forms and strengths of NovoLog/Fiasp. CMS inadvertently excluded NDC-11 00169-2101-12 from the list of NDCs to which any agreed-upon MFP would apply from the files sent on December 28, 2023 and January 31, 2024. CMS has added this NDC-11 to the "MFP NDC Calculator" worksheet in the "Manu_MFP_DFS_IPAY2026_NovoLog_Fiasp_041524.xlsx" Excel file. The updated "Manu_MFP_DFS_IPAY2026_NovoLog_Fiasp_041524.xlsx" Excel file has been uploaded to Box (ADD LINK) and is ready for download. If you are unable to access the link to the revised document, please respond to this email to let us know how you would like to receive them.

As described in section 40.2 of the Revised Guidance, the Primary Manufacturer has an ongoing obligation to timely report any changes to the list of NDC-11s of the selected drug to ensure the list of NDC-11s remains complete and accurate.

Thank you,
CMS Medicare Drug Rebate and Negotiations Group

Subject: Updated MFP Application Across Dosage Forms and Strengths for IPAY 2026

Dear Immunex Corporation,

In accordance with section 1196(a)(2) of the Social Security Act (the Act) and section 60.5 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("revised guidance"), CMS has updated its computation of how any agreed-upon maximum fair price (MFP) will apply across dosage forms and strengths of Enbrel based on Immunex Corporation's resubmission of certain data previously submitted under Section 1194(e)(1) of the Act in the CMS Health Plan Management System.

As described in section 40.5 of the revised guidance, CMS developed the interactive tool for Immunex Corporation that demonstrates how CMS will apply the negotiated MFP across dosage forms and strengths of Enbrel. Given that CMS has updated its computation to incorporate the updates to WAC unit price and WAC total unit volume in response to the CMS email dated July 24, as described in section 40.5 of the revised guidance, a Primary Manufacturer who believes in good faith that CMS has made an error in the computation of how CMS will apply the single MFP across dosage forms and strengths may submit a suggestion of error for CMS' consideration. A Primary Manufacturer has 30 days to submit a suggestion of error and may do so by submitting the request via email to this email box (IRARebateandNegotiation@cms.hhs.gov) with the subject line "Suggestion of Error for Enbrel." CMS will review and respond within 30 days of receiving the suggestion of error from the Primary Manufacturer if feasible.

Please find this updated interactive tool for Enbrel available for download in Box [add Box link]. If you are unable to access the link to the interactive tool, please respond to this email to let us know how you would like to receive it.

Thank you,

CMS Medicare Drug Rebate and Negotiations Group

From: CMS IRA Rebate and Negotiation
To: Callies-Virshup, Michelle (CMS/CM); Folsom, Brennan (CMS/CM); Kane, Corden (CMS/CM); Lockwood, Candice (CMS/CM); Hendrick, Franklin (CMS/CM); Yip, Rebecca (CMS/CM); Esch@man, Brede (CMS/CM)
Subject: FW: Outreach – Additional NDC-11s Identified – Response Needed
Date: Monday, April 8, 2024 4:18:33 PM
Attachments: image001.png
image002.png

Out of Scope

From: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>
Sent: Monday, April 8, 2024 4:11 PM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Cc: Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>; Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>
Subject: RE: Outreach – Additional NDC-11s Identified – Response Needed

CMS,

According to the FDA's National Drug Directory, A-S Medication Solutions ("A-S Medication") is the labeler for NDC-11: 50090-3625-00 (10 mg). This NDC-11 was included in Section A of our initial submission to CMS in October 2023. There, we stated that A-S Medication is not a Primary Manufacturer or a Secondary Manufacturer of Xarelto®.

The FDA's National Drug Directory (reproduced below in part) also states that NDC-11: 50090-3625-00 is not a "Sample Package." This publicly available information is the basis for our response in the third column of the table immediately below.

NDC-11	Marketed/Controlled by the Primary Manufacturer or a Secondary Manufacturer (Y/N)	Sample Package NDC (Y/N)
50090-3625-00	N	N

FDA's National Drug Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm):

Current through April 02, 2024

You have searched Finished drug products

Search Results: 'xarelto'

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page**

Search for text in the table:

Regards,
John Schaeffer

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Monday, April 1, 2024 11:25 AM
To: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>
Subject: [EXTERNAL] Outreach – Additional NDC-11s Identified – Response Needed

Janssen Pharms:

Please find attached a letter regarding additional NDC-11s that we recently identified. We request your review and responses no later than April 8, 2024 at 5pm ET.

Regards,

Medicare Drug Rebate and Negotiations Group

CMS,

In response to your email, stated below is the additional information that the agency should consider prior to any release. J&J reaffirms our recommendation stated in our November 1, 2024 response letter to redact highlighted 3rd party information without expressed approvals from these organizations.

Section 1194(e)(2) Information

Negotiation Data Elements Information Collection Request (OMB 0938-1449) (ICR)
Section: Section I - *Question 28 Attachment Table 2*
Analysource & IQVIA are subscription-based services which require license and/or approval for access or disclosure. https://www.analysource.com/subscription-plans/
IQVIA https://www.iqvia.com/about-us/terms-of-use
The highlighted rows in Table 2 and citation 2 for Question 27, on page 1 of the PDF titled "Rivaroxaban_Xarelto – MFR E2 Submission_Marked" should be redacted under the same condition since they were sourced from IQVIA data through a J&J subscription. CMS must evaluate whether it needs to request its own permission for use in the disclosures and will bear the responsibility to obtain any necessary permissions for its planned use.

ICR Section: Section I - Question 28 Attachment Table 4
Although the studies in the summary table are published, some information (conversion of rates, absolute risk difference) was not included in all the publications or had to be calculated. This internal developed summary outside publication should be redacting.

ICR Section: Section I - Question 28 Attachment Figure 1 & 2
It is not clear how the information submitted was used in the basis of evaluating price. While publicly accessible online, these materials are owned by a third party and CMS must evaluate whether it needs to request its own permission for use in the disclosures and will bear the responsibility to obtain any necessary permissions for its planned use.

Attendee Report,
Report Generated:,"Jan 14, 2025 1:55 PM"
Topic,Webinar ID,Actual Start Time,Actual Duration (minutes),# Registered,# Cancelled,Unique Viewers,Total Users,Max Concurrent Views,Enable Registration
January 2025 Manufacturer Technical Call,160 045 8334,"Jan 14, 2025 12:48 PM",60,383,1,176,221,187,Yes
Host Details,
Attended,User Name (Original Name),Email,Join Time,Leave Time,Time in Session (minutes),Is Guest,Country/Region Name
Yes,"Tom Scholfield (he|him), MITRE",m35875@mitre.org,"Jan 14, 2025 12:50:50","Jan 14, 2025 13:47:34",57,No,United States
Panelist Details,
Attended,User Name (Original Name),Email,Join Time,Leave Time,Time in Session (minutes),Is Guest,Country/Region Name
Yes,John Coster# CMS (Panelist), (b)(6) ,"Jan 14, 2025 12:50:24","Jan 14, 2025 13:47:32",58,Yes,United States
Yes,Lara Strawbridge# CMS (Panelist), (b)(6) "Jan 14, 2025 12:52:37","Jan 14, 2025 13:47:32",55,Yes,United States
Yes,Brennan Folsom# CMS (Panelist), (b)(6) ,"Jan 14, 2025 12:52:59","Jan 14, 2025 13:47:35",55,Yes,United States
Yes,Michelle Callies-Virshup# CMS (Panelist), (b)(6) "Jan 14, 2025 12:56:28","Jan 14, 2025 13:47:34",52,Yes,United States
Yes,Chris Ritter (Panelist), (b)(6) "Jan 14, 2025 12:56:32","Jan 14, 2025 13:47:34",52,Yes,United States
Yes,Janet Brock# CMS (Panelist), (b)(6) "Jan 14, 2025 12:56:46","Jan 14, 2025 13:47:31",51,Yes,United States
Yes,Mike McCormick# CMS (Panelist) (b)(6) "Jan 14, 2025 12:58:16","Jan 14, 2025 13:47:33",50,Yes,United States
Yes,Panelist, (b)(6) "Jan 14, 2025 13:04:27","Jan 14, 2025 13:04:36",1,Yes,United States
Yes,Abigail Painchaud,apainchaud@mitre.org,"Jan 14, 2025 12:48:15","Jan 14, 2025 13:47:35",60,No,United States
Attendee Details,
Attended,User Name (Original Name),First Name,Last Name,Email,Organization,Registration Time,Approval Status,Join Time,Leave Time,Time in Session (minutes),Is Guest,HPMS ID/Contract ID,Country/Region Name
No,Cheri,Cheri,Rice ,cheri.rice@cms.hhs.gov,CMS,"Dec 13, 2024 16:15:27",approved,--,--,--,--,JanMnfrCall,,
No,Claire,Claire,Hutchinson,claire.hutchinson@cms.hhs.gov,CMS,"Dec 13, 2024 16:16:35",approved,--,--,--,--,JanMnfrCall,,
Yes,Anjali Daya,Anjali,Daya,anjali.daya@cms.hhs.gov,CMS,"Dec 16, 2024 09:29:13",approved,"Jan 14, 2025 13:02:50","Jan 14, 2025 13:47:34",45,Yes,JanMnfrCall,United States,
No,Nicholas,Nicholas,Lynn,nicholas.lynn@cms.hhs.gov,CMS,"Dec 18, 2024 12:12:39",approved,--,--,--,--,JanMnfrCall,,

No,Dana,Dana,Haynes,dana.haynes@cms.hhs.gov,Centers for Medicare and Medicaid,"Dec 18, 2024 12:13:48",approved,--,--,--,--,JanMnfrCall,,
No,Mary,Mary,Ellis,mary.ellis@cms.hhs.gov,CMS,"Dec 18, 2024 12:19:57",approved,--,--,--,--,JanMnfrCall,,
No,Kelly,Kelly,Szafara,kelly.szafara1@cms.hhs.gov,CMS,"Dec 18, 2024 12:24:09",approved,--,--,--,--,P1234,,
No,Krysta,Krysta,Aulak,krystamarie.aulak@cms.hhs.gov,CMS,"Dec 18, 2024 12:31:15",approved,--,--,--,--,JanMnfrCall,,
No,Ananya,Ananya,Kalahasti,ananya.kalahasti@cms.hhs.gov,MDRNG,"Dec 18, 2024 12:35:20",approved,--,--,--,--,JanMnfrCall,,
Yes,Michelle Robinson,Michelle,Robinson,michelle.robinson@cms.hhs.gov,CMS,"Dec 18, 2024 12:41:38",approved,"Jan 14, 2025 13:02:07","Jan 14, 2025 13:47:33",46,Yes,JanMnfrCall,United States,
No,steven,steven,selde,steven.selde@cms.hhs.gov,cms / mdrng,"Dec 18, 2024 13:43:23",approved,--,--,--,--,s4zg,,
No,Ritu,Ritu,Sharma,ritu.sharma@cms.hhs.gov,CMS,"Dec 18, 2024 14:51:04",approved,--,--,--,--,JanMnfrCall,,
No,Ross,Ross,Glasser,ross.glasser@cms.hhs.gov,CMS,"Dec 18, 2024 15:27:12",approved,--,--,--,--,JanMnfrCall,,
No,Andres,Andres,Pulido,andres.pulido@apellis.com,Apellis Pharmaceutical,"Dec 18, 2024 16:08:08",approved,--,--,--,--,P3KY,,
Yes,Amy Trent,Amy,Trent,amy.trent@grifols.com,"Grifols USA, LLC","Dec 18, 2024 16:13:38",approved,"Jan 14, 2025 13:02:44","Jan 14, 2025 13:47:35",45,Yes,P1117,United States,
Yes,BingBing Song,BingBing,Song,bingbing.song@bmrn.com,BioMarin,"Dec 18, 2024 16:15:43",approved,"Jan 14, 2025 13:02:00","Jan 14, 2025 13:44:04",43,Yes,P1023,United States,
No,Anh,Anh,Tran,atran7@hap.org,Health Alliance Plan,"Dec 18, 2024 16:20:40",denied,--,--,--,--,H2354,,
Yes,Dalton Wilkins,Dalton,Wilkins,dalton_wilkins@pharmaessentia.com,PharmaEssentia,"Dec 18, 2024 16:21:49",approved,"Jan 14, 2025 13:09:23","Jan 14, 2025 13:47:33",39,Yes,P1530,United States,
Yes,Darnell Turner,Darnell,Turner,dturner@exelixis.com,Exelixis,"Dec 18, 2024 16:23:34",approved,"Jan 14, 2025 13:04:23","Jan 14, 2025 13:32:56",29,Yes,P1350,United States,
Yes,Audrey Fletcher,Audrey,Fletcher,audrey.fletcher@beigene.com,"BeiGene USA, Inc.","Dec 18, 2024 16:24:19",approved,"Jan 14, 2025 13:01:06","Jan 14, 2025 13:31:26",31,Yes,P1617,United States,
Yes,Daniel Gatzke,Daniel,Gatzke,dgatzke@collegiumpharma.com,Collegium Pharmaceutical,"Dec 18, 2024 16:24:44",approved,"Jan 14, 2025 13:03:43","Jan 14, 2025 13:47:35",44,Yes,P1441,United States,
Yes,Mona Watkins,Mona,Watkins,mona.watkins@chiesi.com,"Chiesi USA, Inc.","Dec 18, 2024 16:27:17",approved,"Jan 14, 2025 13:00:35","Jan 14, 2025 13:47:30",47,Yes,P1064,United States,

Yes,Jared Michaud,Jared,Michaud,jmichaud@exelixis.com,Exelixis,"Dec 18, 2024 16:28:07",approved,"Jan 14, 2025 13:01:09","Jan 14, 2025 13:47:34",47,Yes,P1350,United States,
Yes,Cathy Miller,Cathy,Miller,cmiller@pricing-group.com,The Pricing Group,"Dec 18, 2024 16:29:08",approved,"Jan 14, 2025 13:00:56","Jan 14, 2025 13:47:34",47,Yes,P1846,United States,
Yes,Ed Schmitt,Ed,Schmitt,edward.schmitt@bms.com,BMS,"Dec 18, 2024 16:33:31",approved,"Jan 14, 2025 13:00:33","Jan 14, 2025 13:47:34",48,Yes,P1002,United States,
No,CHRIS,CHRIS,ROFIDAL,crofidal@unither.com,United Therapeutics Corporation,"Dec 18, 2024 16:37:37",approved,--,--,--,--,P1186,,
Yes,Alex Wolfe,Alex,Wolfe,alex.wolfe@lilly.com,Eli Lilly and Company,"Dec 18, 2024 16:41:31",approved,"Jan 14, 2025 13:12:26","Jan 14, 2025 13:47:34",36,Yes,P1022,United States,
Yes,Jenny Bulkin,Jenny,Bulkin,jenny@wovendata.com,Woven Data,"Dec 18, 2024 16:41:44",approved,"Jan 14, 2025 13:01:18","Jan 14, 2025 13:16:14",15,Yes,P1842,United States,
Yes,Jennifer Bobo,Jennifer,Bobo,jennifer.bobo@cms.hhs.gov,CMS MDRNG,"Dec 18, 2024 16:42:07",approved,"Jan 14, 2025 13:00:37","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
No,Keating,Keating,Kuhn,keating.kuhn@beigene.com,BeiGene,"Dec 18, 2024 16:42:59",approved,--,--,--,--,P1617,,
Yes,John Schaeffer,John,Schaeffer,jschaeff@its.jnj.com,Johnson and Johnson,"Dec 18, 2024 16:46:53",approved,"Jan 14, 2025 13:01:56","Jan 14, 2025 13:47:34",46,Yes,P1135 and P1243,United States,
No,Gretel ,Gretel ,Gonzalez,ggonzalez@solishealthplans.com,Solis Health Plans,"Dec 18, 2024 16:48:31",denied,--,--,--,--,H0982,,
No,Jamie,Jamie,Cresto,cresto@vivus.com,VIVUS LLC,"Dec 18, 2024 16:51:11",approved,--,--,--,--,P1136,,
No,Kelly,Kelly,Wilson,wilson.kelly@securityhealth.org,Security Health Plan of WI,"Dec 18, 2024 16:53:24",denied,--,--,--,--,H5211,,
Yes,Irene Coleman,Irene,Coleman,irene.coleman@indivior.com,Indivior Inc,"Dec 18, 2024 16:53:38",approved,"Jan 14, 2025 13:00:38","Jan 14, 2025 13:47:33",47,Yes,P1144,United States,
No,Anthony,Anthony,Titcombe,anthony.titcombe@alvogen.com,"Alvogen, Inc.","Dec 18, 2024 16:55:40",approved,--,--,--,--,P1310,,
No,David,David,Schwartz,David.Schwartz@alvogen.com,"Alvogen, Inc.","Dec 18, 2024 16:57:17",approved,--,--,--,--,P1310,,
Yes,Lisa Elvin,Lisa,Elvin,Lisa.Elvin@alvogen.com,"Alvogen, Inc.","Dec 18, 2024 16:59:05",approved,"Jan 14, 2025 13:00:34","Jan 14, 2025 13:47:34",47,Yes,P1310,United States,
No,Laura,Laura,Witherspoon,laura.c.witherspoon@gsk.com,GSK,"Dec 18, 2024 17:00:37",approved,--,--,--,--,P1101,,
Yes,Treasure Boyle,Treasure,Boyle,treasure.t.boyle@gsk.com,GlaxoSmithKline,"Dec 18, 2024 17:01:18",approved,"Jan 14, 2025 13:01:01","Jan 14, 2025 13:47:34",47,Yes,P1101,United States,

No,Lyssa,Lyssa,Zhao,lzhao@securabio.com,"Secura Bio, INC","Dec 18, 2024 17:02:56",approved,--,--,--,--,P1664,,
No,Raksha,Raksha,Dondapati,Raksha.x.dondapati@gsk.com,GSK,"Dec 18, 2024 17:03:37",approved,--,--,--,--,PH1101,,
No,Lisa,Lisa,Kiniklis,lkiniklis@deciphera.com,Deciphera Pharmaceuticals LLC,"Dec 18, 2024 17:03:59",approved,--,--,--,--,P1658,,
No,Debbie,Debbie,Ward,dward@amhealthplans.com,Mitchell Family Office,"Dec 18, 2024 17:04:14",denied,--,--,--,--,H7779,,
Yes,Kristi Thompson,Kristi,Thompson,kristi.g.thompson@gsk.com,GSK,"Dec 18, 2024 17:04:27",approved,"Jan 14, 2025 13:03:54","Jan 14, 2025 13:47:28",44,Yes,PH1101,United States,
Yes,Shola Oko-osi,Shola,Oko-osi,aokoosi@arcutis.com,Arcutis,"Dec 18, 2024 17:09:39",approved,"Jan 14, 2025 13:04:30","Jan 14, 2025 13:47:34",44,Yes,ONVP,United States,
No,Chad,Chad,Nagel,cnagel@marinuspharma.com,"Marinus Pharmaceuticals, Inc.","Dec 18, 2024 17:10:44",approved,--,--,--,--,P1749,,
No,jesse,jesse,Mensah,jesse.adjetey-mensah@Freseniusmedicalcare.com,Fresenius Medical Care,"Dec 18, 2024 17:14:16",approved,--,--,--,--,P1185,,
Yes,Odalys Caprisecca,Odalys,Caprisecca,odalys.caprisecca@novartis.com,Novartis,"Dec 18, 2024 17:15:51",approved,"Jan 14, 2025 13:00:53","Jan 14, 2025 13:47:34",47,Yes,P1008,United States,
Yes,kim storino,kim,storino,kimberly.w.storino@gsk.com,GSK,"Dec 18, 2024 17:19:50",approved,"Jan 14, 2025 13:02:16","Jan 14, 2025 13:47:34",46,Yes,P1101,United States,
Yes,kim storino,kim,storino,kimberly.w.storino@gsk.com,,,,"Jan 14, 2025 13:02:22","Jan 14, 2025 13:47:34",46,Yes,,United States
Yes,Josephine Cosentino,Josephine,Cosentino,josephine.cosentino@boehringer-ingelheim.com,Boehringer Ingelheim,"Dec 18, 2024 17:21:16",approved,"Jan 14, 2025 13:16:22","Jan 14, 2025 13:47:34",32,Yes,P1125,United States,
Yes,Roneil Narciso,Roneil,Narciso,rnarciso@aveooncology.com,"AVEO Pharmaceuticals, Inc.","Dec 18, 2024 17:21:55",approved,"Jan 14, 2025 13:01:24","Jan 14, 2025 13:47:34",47,Yes,P1363,United States,
Yes,Michele Burkwald,Michele,Burkwald,mburkwald@federalcompliancesolutions.com,Federal Compliance Solutions LLC,"Dec 18, 2024 17:22:27",approved,"Jan 14, 2025 13:00:49","Jan 14, 2025 13:47:34",47,Yes,B3ZE,United States,
Yes,Matt Sheffield,Matt,Sheffield,matt.sheffield@tevapharm.com,Teva,"Dec 18, 2024 17:22:40",approved,"Jan 14, 2025 13:00:38","Jan 14, 2025 13:47:34",47,Yes,SZKV,United States,
Yes,Matt Sheffield,Matt,Sheffield,matt.sheffield@tevapharm.com,,,,"Jan 14, 2025 13:05:28","Jan 14, 2025 13:06:24",1,Yes,,United States
Yes,Matt Sheffield,Matt,Sheffield,matt.sheffield@tevapharm.com,,,,"Jan 14, 2025 13:07:46","Jan 14, 2025 13:47:35",40,Yes,,United States
Yes,Michelle Lucas,Michelle,Lucas,michelle.lucas@takeda.com,"Takeda Pharmaceuticals America, Inc.","Dec 18, 2024 17:22:47",approved,"Jan 14, 2025 13:02:05","Jan 14, 2025 13:47:35",46,Yes,LQHP,United States,

Yes,Katie Lapins Trujillo,Katie,Lapins Trujillo,klapinstrujillo@pricing-group.com,The Pricing Group,"Dec 18, 2024 17:23:35",approved,"Jan 14, 2025 13:00:31","Jan 14, 2025 13:18:53",19,Yes,P1846,United States,
No,Linda ,Linda ,Wolcheski,linda.wolcheski@boehringer-ingelheim.com,"Boehringer Ingelheim Pharmaceuticals, Inc.","Dec 18, 2024 17:24:36",approved,--,--,--,--,1125,,
No,Matt,Matt,Bauman,matthew.bauman@viatris.com,Viatris (Mylan),"Dec 18, 2024 17:24:40",approved,--,--,--,--,P1059,,
Yes,Maia Larsson,Maia,Larsson,maia.larsson@cms.hhs.gov,CMS,"Dec 18, 2024 17:27:22",approved,"Jan 14, 2025 13:01:04","Jan 14, 2025 13:47:33",47,Yes,00000,United States,
No,Mitchell,Mitchell,DeLoach,mdeloach@kowapharma.com,Kowa Pharmaceuticals America,"Dec 18, 2024 17:28:09",approved,--,--,--,--,d46g,,
Yes,Ron Hartmann,Ron,Hartmann,rhartmann@sagentpharma.com,Sagent Pharmaceuticals,"Dec 18, 2024 17:28:59",approved,"Jan 14, 2025 13:02:06","Jan 14, 2025 13:47:32",46,Yes,P1596,United States,
No,Ben,Ben,Blodgett,Benjamin.Blodgett@us.nestle.com,"Aimmune Therapeutics, Inc.","Dec 18, 2024 17:36:23",approved,--,--,--,--,P1659,,
No,Jennifer,Jennifer,Crosswell,jennifer.crosswell@azurity.com,Azurity Pharmaceuticals,"Dec 18, 2024 17:40:03",approved,--,--,--,--,P1133,,
Yes,Brittany Tanner,Brittany,Tanner,bdockter@amgen.com,Amgen,"Dec 18, 2024 17:43:00",approved,"Jan 14, 2025 13:00:59","Jan 14, 2025 13:47:34",47,Yes,P1177,United States,
No,Ronald,Ronald,Pomerantz, (b)(6) ,Independent,"Dec 18, 2024 17:46:04",denied,--,--,--,--,P6pt,,
Yes,Ramon Perez,Ramon,Perez,ramon.pereziii@pfizer.com,Pfizer Inc.,"Dec 18, 2024 17:56:04",approved,"Jan 14, 2025 13:14:26","Jan 14, 2025 13:47:33",34,Yes,PFKL,United States,
Yes,Paul Aynilian,Paul,Aynilian,paul.j.aynilian@abbvie.com,AbbVie,"Dec 18, 2024 17:56:07",approved,"Jan 14, 2025 13:03:29","Jan 14, 2025 13:07:23",4,Yes,P-1003,United States,
No,Rakesh,Rakesh,Chand,chand@vivus.com,VIVUS LLC,"Dec 18, 2024 18:26:19",approved,--,--,--,--,P1136,,
Yes,Linda Kamin,Linda,Kamin,linda.kamin@bms.com,Bristol Myers Squibb,"Dec 18, 2024 18:26:32",approved,"Jan 14, 2025 13:02:02","Jan 14, 2025 13:47:34",46,Yes,P1002,United States,
No,Beckie,Beckie,Peyton,beckie.peyton@cms.hhs.gov,CMS,"Dec 18, 2024 18:30:33",approved,--,--,--,--,P1234,,
No,Dan,Dan,Valese,dan.valese@pfizer.com,Pfizer,"Dec 18, 2024 18:35:32",approved,--,--,--,--,P1077,,
Yes,Chinwe Nwoye,Chinwe,Nwoye,cenus@leo-pharma.com,LEO Pharma Inc,"Dec 18, 2024 18:36:45",approved,"Jan 14, 2025 13:02:36","Jan 14, 2025 13:47:34",45,Yes,NQMK,United States,
Yes,Mike Rowland,Mike,Rowland,mike.rowland@acadia-pharm.com,Acadia Pharmaceuticals Inc.,"Dec 18, 2024 18:39:06",approved,"Jan 14, 2025 13:01:20","Jan 14, 2025 13:42:19",41,Yes,P1405,United States,

No,Eileen,Eileen,Murphy,murphy.eileen@securityhealth.org,Security Health Plan,"Dec 18, 2024 19:07:28",denied,--,--,--,--,H5211,,
No,Kathy,Kathy,Kulkarni,katk@asendispharma.com,Ascendis Pharma,"Dec 18, 2024 19:29:26",approved,--,--,--,--,P1615,,
Yes,Wanda Agrinsoni,Wanda,Agrinsoni,wagrinsoni@ascendlaboratories.com,"Ascend Laboratories, LLC.","Dec 18, 2024 19:31:45",approved,"Jan 14, 2025 13:01:07","Jan 14, 2025 13:47:35",47,Yes,P1090,United States,
No,Lisa,Lisa,Piepenburg,lpiepenburg@humana.com,Humana,"Dec 18, 2024 19:33:01",denied,--,--,--,--,P0CM,,
No,Ryan,Ryan,Swenson,ryan.swenson@milliman.com,"Milliman, Inc.","Dec 18, 2024 19:34:46",denied,--,--,--,--,s7gw,,
Yes,Andrea Braciska,Andrea,Braciska,andrea.braciska@biogen.com,Biogen,"Dec 18, 2024 19:36:30",approved,"Jan 14, 2025 13:00:30","Jan 14, 2025 13:47:30",47,Yes,BQEU/XP1081,United States,
No,John,John,Bergmann,John_Bergmann@merck.com,Merck,"Dec 18, 2024 19:48:27",approved,--,--,--,--,P1004,,
Yes,Shannon McCrudden,Shannon,McCrudden,shannon.mccrudden@novartis.com,Novartis Pharmaceutical Corp,"Dec 18, 2024 20:12:38",approved,"Jan 14, 2025 13:01:14","Jan 14, 2025 13:47:34",47,Yes,P1008,United States,
No,Jessica,Jessica,Beck,jessica.beck@amarincorp.com,"Amarin Pharma, Inc","Dec 18, 2024 20:15:39",approved,--,--,--,--,P1326,,
Yes,Neelam Shah,Neelam,Shah,neelam.shah@pfizer.com,Pfizer,"Dec 18, 2024 20:47:21",approved,"Jan 14, 2025 13:01:10","Jan 14, 2025 13:01:32",1,Yes,P1077,United States,
Yes,Neelam Shah,Neelam,Shah,neelam.shah@pfizer.com,,,,"Jan 14, 2025 13:01:45","Jan 14, 2025 13:47:34",46,Yes,,United States
No,Karen,Karen,Rees,krees1@thepaceplace.org,The Pace Place,"Dec 18, 2024 21:32:46",denied,--,--,--,--,H7469,,
No,Bernard,Bernard,Crerand,Bernard.crerand@emdserono.com,EMD Serono,"Dec 18, 2024 22:18:13",approved,--,--,--,--,44087,,
Yes,Ryan Sullivan,Ryan,Sullivan,ryan.sullivan@galderma.com,Galderma,"Dec 18, 2024 22:37:48",approved,"Jan 14, 2025 13:01:28","Jan 14, 2025 13:47:32",47,Yes,SKE3,United States,
No,Rebecca,Rebecca,Yip,rebecca.yip@cms.hhs.gov,CMS,"Dec 18, 2024 23:21:14",approved,--,--,--,--,JanMnfrCall,,
Yes,Darpan Jhaveri,Darpan,Jhaveri,darpan.jhaveri@insmed.com,Insmed,"Dec 18, 2024 23:24:23",approved,"Jan 14, 2025 13:00:43","Jan 14, 2025 13:11:54",12,Yes,P1385,United States,
Yes,Elena Sampson,Elena,Sampson,Elena.Sampson@Helsinn.com,"Helsinn Therapeutics (U.S.), Inc.","Dec 19, 2024 06:51:24",approved,"Jan 14, 2025 13:03:59","Jan 14, 2025 13:47:33",44,Yes,P1461,United States,
No,Carolyn,Carolyn,Heckert,cmheckert@pertzye.com,"Digestive Care, Inc.","Dec 19, 2024 07:44:22",approved,--,--,--,--,P1167,,
Yes,Mary Jo Farinella-Evans,Mary Jo,Farinella-Evans,maryjo.farinella@glenmarkpharma.com,"Glenmark Pharmaceuticals Inc., USA","Dec 19,

2024 07:50:04",approved,"Jan 14, 2025 13:00:37","Jan 14, 2025 13:47:34",47,Yes,1267,United States,
No,Todd,Todd,Sponenberg,tsponenberg@geisinger.edu,Geisinger Health Plan,"Dec 19, 2024 07:51:39",denied,--,--,--,--,H3954,,
No,Jaime,Jaime,Houghton,jhoughton@uphp.com,Upper Peninsula Health Plan,"Dec 19, 2024 08:11:35",denied,--,--,--,--,H1977,,
No,Randy,Randy,Maloziec,randy.maloziec@immunocore.com,IMMUNOCORE,"Dec 19, 2024 08:12:07",approved,--,--,--,--,p1689,,
No,Deanna,Deanna,Homer,dhomer@htanc.com,Care N Care insurance Company of North Carolina d/b/a HealthTeam Advantage,"Dec 19, 2024 08:23:31",denied,--,--,--,--,H9808,,
No,Molly,Molly,Pelzer,molly.pelzer@cms.hhs.gov,CMS/CM/MDRNG,"Dec 19, 2024 08:24:42",approved,--,--,--,--,JanMnfrCall,,
Yes,Sydney Finamore,Sydney,Finamore,sydney.finamore@cms.hhs.gov,CMS,"Dec 19, 2024 08:35:39",approved,"Jan 14, 2025 13:27:41","Jan 14, 2025 13:47:34",20,Yes,JanMnfrCall,United States,
No,Sharon,Sharon,Essi,sessi@challiance.org,CHA PACE,"Dec 19, 2024 08:47:48",denied,--,--,--,--,H2221,,
Yes,Kelly Echols,Kelly,Echols,kechols@axsome.com,"Axsome Therapeutics, Inc.","Dec 19, 2024 08:48:56",approved,"Jan 14, 2025 13:00:57","Jan 14, 2025 13:47:33",47,Yes,P1764,United States,
Yes,Kelly Echols,Kelly,Echols,kechols@axsome.com,,,,"Jan 14, 2025 13:03:25","Jan 14, 2025 13:35:53",33,Yes,,United States
Yes,Kelly Echols,Kelly,Echols,kechols@axsome.com,,,,"Jan 14, 2025 13:07:52","Jan 14, 2025 13:47:34",40,Yes,,United States
No,Sara Beth ,Sara Beth ,Brown,sbrown@htanc.com,HealthTeam Advantage,"Dec 19, 2024 08:51:21",denied,--,--,--,--,H9808,,
Yes,Katherine Carpenter,Katherine,Carpenter,kcarpenter@radiuspharm.com,"Radius Health, Inc.","Dec 19, 2024 09:07:11",approved,"Jan 14, 2025 13:01:12","Jan 14, 2025 13:47:34",47,Yes,XP1496,United States,
No,Rose,Rose,Rutledge-Glazov,rrglazov@jeffersonhealthplans.com,Jefferson Health Plans,"Dec 19, 2024 09:10:42",denied,--,--,--,--,H9207,,
No,Dayna,Dayna,Altom,altomd@region7aaa.org,Sunrise PACE,"Dec 19, 2024 09:15:10",denied,--,--,--,--,H9052,,
No,Jack,Jack,Geisser ,jgeisser@bio.org,BIO,"Dec 19, 2024 09:18:47",approved,--,--,--,--,JanMnfrCall,,
No,Juliana,Juliana,Reed,juliana@biosimilarsforum.org,Biosimilars Forum,"Dec 19, 2024 09:19:41",approved,--,--,--,--,JanMnfrCall,,
No,Lisa,Lisa,Fleury,Lisa.Fleury@reatapharma.com,Reata Pharma,"Dec 19, 2024 09:20:55",approved,--,--,--,--,JanMnfrCall,,
No,Crystal,Crystal,Kuntz,ckuntz@bio.org,BIO,"Dec 19, 2024 09:22:58",approved,--,--,--,--,JanMnfrCall,,
No,Will,Will,Cromarty,wcromarty@bio.org,BIO,"Dec 19, 2024 09:23:27",approved,--,--,--,--,JanMnfrCall,,
No,Andy,Andy,Cosgrove,acosgrove@bio.org,BIO,"Dec 19, 2024 09:23:59",approved,--,--,--,--,JanMnfrCall,,

No,Sharon,Sharon,Belmont,sbelmont@bio.org,BIO,"Dec 19, 2024 09:24:27",approved,--,--,--,--,JanMnfrCall,,
No,Barbara ,Barbara ,Morgan,bmorgan@cvpace.org,Central Valley PACE,"Dec 19, 2024 09:25:13",denied,--,--,--,--,H1228,,
No,Steve,Steve,Selde,steven.selde@accessiblemeds.org,Accessible Meds,"Dec 19, 2024 09:25:48",approved,--,--,--,--,JanMnfrCall,,
No,Monet,Monet,Stanford,monet.stanford@accessiblemeds.org,Accessible Meds,"Dec 19, 2024 09:26:50",approved,--,--,--,--,JanMnfrCall,,
Yes,Craig Burton,Craig,Burton,Craig.burton@accessiblemeds.org,Accessible Meds,"Dec 19, 2024 09:27:23",approved,"Jan 14, 2025 13:00:50","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
No,yasmeen,yasmeen,Hamdan,yhamdan@bio.org,BIO,"Dec 19, 2024 09:27:54",approved,--,--,--,--,JanMnfrCall,,
No,Bela,Bela,Sastry,bela.sastry@sunovion.com,PhRMA,"Dec 19, 2024 09:28:29",approved,--,--,--,--,JanMnfrCall,,
Yes,Thayer Roberts,Thayer,Roberts,troberts@thornrun.com,Thornrun,"Dec 19, 2024 09:28:57",approved,"Jan 14, 2025 13:02:06","Jan 14, 2025 13:05:02",3,Yes,JanMnfrCall,United States,
Yes,Thayer Roberts,Thayer,Roberts,troberts@thornrun.com,,,,"Jan 14, 2025 13:04:43","Jan 14, 2025 13:47:34",43,Yes,,United States
No,Corbin,Corbin,Santo,csanto@phrma.org,Phrma,"Dec 19, 2024 09:29:24",approved,--,--,--,--,JanMnfrCall,,
No,debjani,debjani,mukherjee,dmukherjee@pcmanet.org,PCMA,"Dec 19, 2024 09:29:41",denied,--,--,--,--,00,,
No,Sylvia,Sylvia,Yu,syu@phrma.org,Phrma,"Dec 19, 2024 09:29:55",approved,--,--,--,--,JanMnfrCall,,
Yes,Carolyn Ha,Carolyn,Ha,Cha@phrma.org,Phrma,"Dec 19, 2024 09:30:39",approved,"Jan 14, 2025 13:00:52","Jan 14, 2025 13:01:11",1,Yes,JanMnfrCall,United States,
No,Kristen,Kristen,Bernie,kbernie@phrma.org,Phrma,"Dec 19, 2024 09:31:08",approved,--,--,--,--,JanMnfrCall,,
No,Rebecca,Rebecca,Hunt,rhunt@phrma.org,Phrma,"Dec 19, 2024 09:31:32",approved,--,--,--,--,JanMtfCall,,
No,Jocelyn,Jocelyn,Ulrich,julrich@phrma.org,Phrma,"Dec 19, 2024 09:32:18",approved,--,--,--,--,JanMnfrCall,,
No,Karen,Karen,Schwartz,kschwartz@phrma.org,Phrma,"Dec 19, 2024 09:32:49",approved,--,--,--,--,JanMtfCall,,
No,Lauren,Lauren,Neves,lneves@phrma.org,Phrma,"Dec 19, 2024 09:33:14",approved,--,--,--,--,JanMtfCall,,
No,Chrstine,Chrstine,Liow,cliow@novavax.com,Novavax,"Dec 19, 2024 09:34:01",approved,--,--,--,--,JanMnfrCall,,
No,Joyce,Joyce,Alexander-Hines,joyce.alexander-hines@trinity-health.org,LIFE St6. Joseph of the Pines,"Dec 19, 2024 09:34:04",denied,--,--,--,--,H1500,,
No,Judit,Judit,Illes,jilles@ptcbio.com,PTC Therapeutics,"Dec 19, 2024 09:34:29",approved,--,--,--,--,JanMtfCall,,
No,Vadim,Vadim,Lubarsky,vadim.lubarsky@myovant.com,Myovant,"Dec 19, 2024 09:35:07",approved,--,--,--,--,JanMnfrCall,,

No,Michael,Michael,Sargent,michael.sargent@accessiblemeds.org,Accessible Meds,"Dec 19, 2024 09:35:44",approved,--,--,--,--,JanMnfrCall,,
Yes,Melody Calkins,Melody,Calkins,mcalkins@bio.org,BIO,"Dec 19, 2024 09:36:19",approved,"Jan 14, 2025 13:01:00","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
No,Jackie,Jackie,Erdo,jacqueline.erdo@cms.hhs.gov,CMS,"Dec 19, 2024 09:38:46",approved,--,--,--,--,JanMnfrCall,,
No,Rohini,Rohini,Mandal,rohini@coverright.com,CoverRight,"Dec 19, 2024 09:41:55",denied,--,--,--,--,N/A,,
No,Twinkle,Twinkle,Patel,tpatel@itci-inc.com,Intra-Cellular Therapies Inc,"Dec 19, 2024 09:42:52",approved,--,--,--,--,P1602,,
Yes,Kevin Dilk,Kevin ,Dilk,kevin.dilk@lilly.com,Eli Lilly and Company,"Dec 19, 2024 09:44:04",approved,"Jan 14, 2025 13:00:40","Jan 14, 2025 13:47:34",47,Yes,P1022,United States,
No,Melissa,Melissa,Baker,melissa.baker@cms.hhs.gov,CM/MDRNG,"Dec 19, 2024 09:44:38",approved,--,--,--,--,JanMnfrCall,,
No,Jen,Jen,Draudt,draudt.jennifer@endo.com,Endo USA,"Dec 19, 2024 09:49:05",approved,--,--,--,--,1107,,
No,Brent,Brent,Oakleaf,brent.oakleaf@us.sumitomo-pharma.com,SMPA,"Dec 19, 2024 09:49:13",approved,--,--,--,--,P-1086,,
Yes,Lenis De Leon,Lenis,De Leon,ldeleon@radiuspharm.com,Radius Health Inc.,"Dec 19, 2024 09:51:10",approved,"Jan 14, 2025 13:03:50","Jan 14, 2025 13:47:34",44,Yes,XP1496,United States,
Yes,patricia pelaez,patricia,pelaez,pelaez.patricia@endo.com,ENDO USA Inc,"Dec 19, 2024 09:54:28",approved,"Jan 14, 2025 13:00:43","Jan 14, 2025 13:47:34",47,Yes,P1134,United States,
No,Krissy,Krissy,Hurt,krissy@janwerneradultdaycare.org,The basics at Jan Werner,"Dec 19, 2024 10:19:16",denied,--,--,--,--,H4517,,
No,Alexander,Alexander,Santini,alex.santini@arvinas.com,Arvinas,"Dec 19, 2024 10:21:40",approved,--,--,--,--,S850,,
Yes,Donna Macleod,Donna,Macleod,drussnak@shionogi.com,Shionogi,"Dec 19, 2024 10:22:51",approved,"Jan 14, 2025 13:00:46","Jan 14, 2025 13:47:34",47,Yes,P1148,United States,
Yes,Dawn Powell,Dawn,Powell,dawn.powell@astellas.com,Astellas Pharma US Inc.,"Dec 19, 2024 10:23:38",approved,"Jan 14, 2025 13:01:36","Jan 14, 2025 13:47:34",46,Yes,P1127,United States,
No,Daniel,Daniel,Gass,dgass@esperion.com,"Esperion Therapeutics, Inc","Dec 19, 2024 10:25:38",approved,--,--,--,--,P1609,,
No,Rachael,Rachael,Budiwarman,rachael.budiwarman@padagis.com,Padagis US LLC,"Dec 19, 2024 10:28:27",approved,--,--,--,--,P1046,,
Yes,Whitney Hubbard,Whitney,Hubbard,whitney.hubbard@abbvie.com,AbbVie,"Dec 19, 2024 10:31:36",approved,"Jan 14, 2025 13:01:00","Jan 14, 2025 13:47:32",47,Yes,P1003,United States,
No,Corden,Corden,Kane,Corden.Kane2@cms.hhs.gov,CMS,"Dec 19, 2024 10:37:22",approved,--,--,--,--,JanMnfrCall,,

No,Michelle,Michelle,Wojcicki,michelle.wojcicki2@cms.hhs.gov,CMS,"Dec 19, 2024 10:40:46",approved,--,--,--,--,P1234,,
No,Brooke,Brooke,Farney,brooke.farney@healthalliance.org,Health Alliance,"Dec 19, 2024 10:41:50",denied,--,--,--,--,fxge,,
No,Shannon,Shannon,Fanning,Shannon.Fanning@reidhealth.org,Reid Health,"Dec 19, 2024 10:44:21",denied,--,--,--,--,H3522,,
Yes,Jennifer Rozzelle,Jennifer,Rozzelle,jennifer.rozzelle@sanofi.com,Sanofi,"Dec 19, 2024 10:46:20",approved,"Jan 14, 2025 13:01:44","Jan 14, 2025 13:47:34",46,Yes,P1024,United States,
Yes,Mina Ghaies,Mina,Ghaies,Mghaies@medicure.com,Medicure Inc.,"Dec 19, 2024 10:58:19",approved,"Jan 14, 2025 13:00:44","Jan 14, 2025 13:47:34",47,Yes,25208,Canada,
No,Audrey,Audrey,Mahoney,audrey.mahoney@bravenhealth.com,Braven Health,"Dec 19, 2024 10:58:20",denied,--,--,--,--,H0885,,
No,Saria,Saria,Saccoccio,ssaccocio@lumeris.com,Essence Healthcare,"Dec 19, 2024 11:17:28",denied,--,--,--,--,H2610,,
No,Mary,Mary,Kiefer,mary.kiefer@adctherapeutics.com,ADC Therapeutics,"Dec 19, 2024 11:24:26",approved,--,--,--,--,P1740,,
Yes,Amanda DeNucci,Amanda,DeNucci,amanda.denucci@astrazeneca.com,AstraZeneca,"Dec 19, 2024 11:38:23",approved,"Jan 14, 2025 13:00:31","Jan 14, 2025 13:47:34",48,Yes,P1137,United States,
Yes,Amanda DeNucci,Amanda,DeNucci,amanda.denucci@astrazeneca.com,,,,"Jan 14, 2025 13:00:43","Jan 14, 2025 13:32:54",33,Yes,,United States
Yes,Amanda DeNucci,Amanda,DeNucci,amanda.denucci@astrazeneca.com,,,,"Jan 14, 2025 13:00:49","Jan 14, 2025 13:47:34",47,Yes,,United States
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Yes,Amanda DeNucci,Amanda,DeNucci,amanda.denucci@astrazeneca.com,,,,"Jan 14, 2025 13:01:54","Jan 14, 2025 13:47:34",46,Yes,,United States
Yes,Amanda DeNucci,Amanda,DeNucci,amanda.denucci@astrazeneca.com,,,,"Jan 14, 2025 13:31:57","Jan 14, 2025 13:33:48",2,Yes,,United States
Yes,John Nicolosi,John,Nicolosi,john.a.nicolosi@pfizer.com,Pfizer Inc,"Dec 19, 2024 11:43:24",approved,"Jan 14, 2025 13:00:58","Jan 14, 2025 13:47:34",47,Yes,P1077,United States,
Yes,Rebecca Hancock,Rebecca,Hancock,rhancoc1@its.jnj.com,Johnson & Johnson,"Dec 19, 2024 11:51:25",approved,"Jan 14, 2025 13:00:31","Jan 14, 2025 13:47:34",48,Yes,XP1135,United States,
Yes,Christopher Piazza,Christopher,Piazza,christopher.piazza@bayer.com,Bayer,"Dec 19, 2024 11:51:55",approved,"Jan 14, 2025 13:00:49","Jan 14, 2025 13:47:34",47,Yes,P1161,United States,
No,Briana,Briana,Lawson,briana.lawson@piramal.com,Piramal Critical Care,"Dec 19, 2024 12:06:32",approved,--,--,--,--,P1571,,
Yes,Leanne Hawk,Leanne,Hawk,leanne.hawk@grifols.com,"Grifols USA, LLC","Dec 19, 2024 12:31:12",approved,"Jan 14, 2025 13:01:30","Jan 14, 2025 13:47:30",46,Yes,P1117,United States,
No,Michele ,Michele ,Taylor,mtaylor@bioexceltherapeutics.com,BioXcel ,"Dec 19, 2024 12:57:10",approved,--,--,--,--,P1753,,

No,Britney ,Britney ,Johnson,britney.johnson@reidhealth.org,Reid Health PACE,"Dec 19, 2024 13:10:03",denied,--,--,--,--,H3522,,
Yes,Rene Edwards,Rene,Edwards,redwards@argenx.com,argenx,"Dec 19, 2024 13:21:42",approved,"Jan 14, 2025 13:24:12","Jan 14, 2025 13:47:34",24,Yes,P1762,United States,
Yes,Molly Menoni,Molly,Menoni,molly.menoni@bakertilly.com,Orphalan,"Dec 19, 2024 13:31:39",approved,"Jan 14, 2025 13:02:24","Jan 14, 2025 13:47:34",46,Yes,NSSU,United States,
No,Timothy,Timothy,Whiteside,twhiteside@hikma.com,Hikma Pharmaceuticals,"Dec 19, 2024 13:49:44",approved,--,--,--,--,P1242,,
Yes,Kristin Cronkite,Kristin,Cronkite,kcronkite@theactivusgroup.com,the Activus Group,"Dec 19, 2024 13:59:47",approved,"Jan 14, 2025 13:00:41","Jan 14, 2025 13:47:17",47,Yes,P1628,United States,
No,Juan,Juan,Alvarez,jcalvarez@drreddys.com,"Dr. Reddy's Laboratories, Inc. ","Dec 19, 2024 14:05:36",approved,--,--,--,--,P1147,,
Yes,Amy Yenyo,Amy,Yenyo,aqey@novonordisk.com,Novo Nordisk,"Dec 19, 2024 14:21:14",approved,"Jan 14, 2025 13:04:52","Jan 14, 2025 13:47:34",43,Yes,1029,United States,
No,Scott,Scott,Watson,scott.watson@bms.com,Bristol Myers Squibb,"Dec 19, 2024 14:44:42",approved,--,--,--,--,P1002,,
No,samantha,samantha,Blue,sblue@lifeseniorservices.org,LIFE PACE,"Dec 19, 2024 14:45:55",denied,--,--,--,--,H6941,,
Yes,Cole Swigert,Cole,Swigert,co.swigert@prasco.com,"Prasco, LLC","Dec 19, 2024 14:53:33",approved,"Jan 14, 2025 13:00:47","Jan 14, 2025 13:47:34",47,Yes,P1060,United States,
Yes,Cole Swigert,Cole,Swigert,co.swigert@prasco.com,,,,"Jan 14, 2025 13:00:59","Jan 14, 2025 13:47:34",47,Yes,,United States
Yes,Cole Swigert,Cole,Swigert,co.swigert@prasco.com,,,,"Jan 14, 2025 13:01:00","Jan 14, 2025 13:01:14",1,Yes,,United States
No,Marcella,Marcella,Lynch,marcella.lynch@chiesi.com,Chiesi,"Dec 19, 2024 15:01:39",approved,--,--,--,--,P1064,,
Yes,Oonagh O'Malley,Oonagh,O'Malley,oonagh.omalley@insmed.com,Insmed Incorporated,"Dec 19, 2024 15:26:46",approved,"Jan 14, 2025 13:00:39","Jan 14, 2025 13:47:34",47,Yes,P1385,United States,
Yes,Naumita Shah,Naumita,Shah,n.shah@pharming.com,Pharming,"Dec 19, 2024 15:34:43",approved,"Jan 14, 2025 13:01:21","Jan 14, 2025 13:47:34",47,Yes,P1549,United States,
Yes,Vivian Wright,Vivian,Wright,vivian.wright@pfizer.com,Pfizer,"Dec 19, 2024 15:44:32",approved,"Jan 14, 2025 13:22:15","Jan 14, 2025 13:47:06",25,Yes,P1077,United States,
Yes,Doug Behm,Doug,Behm,doug.behm@pfizer.com,Pfizer Inc,"Dec 19, 2024 15:45:07",approved,"Jan 14, 2025 13:00:32","Jan 14, 2025 13:47:15",47,Yes,P1077,United States,
Yes,Christopher Cheney,Christopher,Cheney,ccheney@menarinistemline.com,"Stemline Therapeutics, Inc.","Dec 19, 2024 16:01:35",approved,"Jan 14, 2025 13:01:51","Jan 14, 2025 13:47:02",46,Yes,P1629/CFTS,United States,

No,Jacquie,Jacquie,Schlarb,jschlarb@rmhcare.org,RM PACE,"Dec 19, 2024 16:20:19",denied,--,--,--,--,H5167,,
No,Ruby,Ruby,Kennedy,rgreer@meoc.org,MEOC PACE,"Dec 19, 2024 17:06:17",denied,--,--,--,--,H5037,,
No,Ed,Ed,McAdam,ed.mcadam@indivior.com,Indivior Inc.,"Dec 19, 2024 17:18:39",approved,--,--,--,--,P1144,,
No,Ryan,Ryan,Kruger,ryan.kruger@jordanvalley.org,Jordan Valley Senior Care,"Dec 19, 2024 17:23:43",approved,--,--,--,--,H2918,,
No,leslie ,leslie ,von Esch,lvonesch@llu.edu,LLUH-PACE,"Dec 19, 2024 17:44:28",denied,--,--,--,--,H6147,,
No,Katie,Katie,Hougham,khougham@agingihs.org,PACE of Northeast Indiana,"Dec 20, 2024 07:58:58",denied,--,--,--,--,H0235,,
No,Rachel,Rachel,Cramer,cramer_rachel@lilly.com,Eli Lilly and Co,"Dec 20, 2024 08:11:08",approved,--,--,--,--,P1022,,
No,Christa,Christa,Watts,christa.watts@highmark.com,Highmark,"Dec 20, 2024 08:40:26",denied,--,--,--,--,H3917,,
Yes,Afton Wagner,Afton,Wagner,afton.wagner@novartis.com,Novartis,"Dec 20, 2024 09:15:24",approved,"Jan 14, 2025 13:00:33","Jan 14, 2025 13:47:34",48,Yes,P1008,United States,
Yes,Steven Chen,Steven,Chen,steven.chen5@astrazeneca.com,AstraZeneca,"Dec 20, 2024 09:32:41",approved,"Jan 14, 2025 13:01:00","Jan 14, 2025 13:47:35",47,Yes,P11793,United States,
No,Aaron,Aaron,Hoholik,aaron.hoholik@careresources.org,Care Resources,"Dec 20, 2024 09:42:06",denied,--,--,--,--,H5610,,
No,Esther,Esther,Elefant,eelefant@centersplan.com,CPHL,"Dec 20, 2024 09:59:50",denied,--,--,--,--,H6988,,
No,Debbie,Debbie,Risch,Drisch@its.jnj.com,Johnson & Johnson ,"Dec 20, 2024 10:13:55",approved,--,--,--,--,XP1135,,
No,Brandie,Brandie,Ardeno,bardeno@lifepittsburgh.org,LIFE Pittsburgh,"Dec 20, 2024 10:25:42",denied,--,--,--,--,H3918,,
Yes,Sarah Palmer,Sarah,Palmer,Sarah.Palmer@cslbehring.com,CSL Behring,"Dec 20, 2024 12:06:26",approved,"Jan 14, 2025 13:00:30","Jan 14, 2025 13:47:34",48,Yes,1058,United States,
No,Nicole,Nicole,Helt,nhelt@emblemhealth.com,Emblem Health,"Dec 20, 2024 12:11:49",denied,--,--,--,--,H3330,,
No,Kijuana,Kijuana,Wright,kijuana.wright@azblue.com,BCBSAZ,"Dec 20, 2024 12:41:35",denied,--,--,--,--,H0302,,
No,Shannon,Shannon,Nate,ssleeth@amgen.com,Amgen,"Dec 20, 2024 13:12:24",approved,--,--,--,--,P1177,,
Yes,Giana Mandel,Giana,Mandel,gmandel@amgen.com,Amgen,"Dec 20, 2024 13:13:32",approved,"Jan 14, 2025 13:02:13","Jan 14, 2025 13:47:34",46,Yes,P1177,United States,
Yes,Adam Davies,Adam,Davies,adam.davies@cms.hhs.gov,CMS,"Dec 20, 2024 15:43:56",approved,"Jan 14, 2025 13:00:36","Jan 14, 2025 13:47:34",47,Yes,P1234,United States,

Yes,Adam Davies,Adam,Davies,adam.davies@cms.hhs.gov,,,,"Jan 14, 2025 13:00:42","Jan 14, 2025 13:47:34",47,Yes,,United States
Yes,Adam Davies,Adam,Davies,adam.davies@cms.hhs.gov,,,,"Jan 14, 2025 13:00:59","Jan 14, 2025 13:47:32",47,Yes,,United States
Yes,Adam Davies,Adam,Davies,adam.davies@cms.hhs.gov,,,,"Jan 14, 2025 13:01:01","Jan 14, 2025 13:47:34",47,Yes,,United States
Yes,Adam Davies,Adam,Davies,adam.davies@cms.hhs.gov,,,,"Jan 14, 2025 13:02:10","Jan 14, 2025 13:47:07",45,Yes,,United States
Yes,Adam Davies,Adam,Davies,adam.davies@cms.hhs.gov,,,,"Jan 14, 2025 13:08:00","Jan 14, 2025 13:47:34",40,Yes,,United States
No,Douglas,Douglas,Tennison,ktennison@kalvista.com,KalVista,"Dec 20, 2024 16:49:51",approved,--,--,--,--,P1787,,
Yes,Eric Stuart,Eric,Stuart,eric.stuart@cms.hhs.gov,CMS,"Dec 20, 2024 17:24:21",approved,"Jan 14, 2025 13:04:47","Jan 14, 2025 13:47:34",43,Yes,HHS/CMS/CM/MDRNG/DMDIRO,United States,
No,Steve,Steve,Soman,Steve.Soman@apex4health.com,Memorial Hermann Health Plan,"Dec 20, 2024 17:38:10",denied,--,--,--,--,H7115,,
Yes,Tanuja Gohil,Tanuja,Gohil,tgoh@novonordisk.com,NovoNordisk,"Dec 21, 2024 08:30:05",approved,"Jan 14, 2025 13:00:38","Jan 14, 2025 13:47:35",47,Yes,P1029,United States,
No,Leo,Leo,Yasinski,Leo.yasinski@istx.com,Innoviva Specialty Therapeutics,"Dec 22, 2024 02:42:11",approved,--,--,--,--,71773,,
No,Nisha,Nisha,Koria,nisha.koria@regeneron.com,Regeneron Pharmaceuticals,"Dec 22, 2024 21:55:49",approved,--,--,--,--,1202,,
No,Sefanit,Sefanit,Goshu,sefanit.goshu@apex4health.com,Memorial Hemrann Health Plan,"Dec 23, 2024 09:25:22",denied,--,--,--,--,H7115,,
No,Karissa,Karissa,Wissell,kwissell@pharmastar.com,Anewhealth dba Pharmastar PBM LLC,"Dec 23, 2024 09:39:15",denied,--,--,--,--,H1111,,
Yes,Mary Mullaney,Mary,Mullaney,mary.mullaney@cms.hhs.gov,CMS,"Dec 23, 2024 09:51:55",approved,"Jan 14, 2025 13:05:01","Jan 14, 2025 13:47:32",43,Yes,P1234,United States,
No,Nadia,Nadia,Columbia,nadiacolumbia@cap-rx.com,Capital Rx,"Dec 23, 2024 11:08:02",denied,--,--,--,--,H3204,,
Yes,Caroline Tucker,Caroline,Tucker,caroline.tucker@bms.com,BMS,"Dec 23, 2024 11:47:09",approved,"Jan 14, 2025 13:00:57","Jan 14, 2025 13:47:32",47,Yes,P1002,United States,
No,Devon,Devon,Lara,dlara@mitre.org,MITRE,"Dec 23, 2024 14:00:24",cancelled by host,--,--,--,--,JanMnfrCall,,
No,Doug,Doug,Bornstein,doug.bornstein@alexion.com,Alexion,"Dec 23, 2024 14:50:08",approved,--,--,--,--,P1139,,
No,Emily,Emily,McPherson,emcpherson@mitre.org,Test,"Dec 23, 2024 14:54:28",approved,--,--,--,--,test,,
Yes,Kim Bridgewater,Kim,Bridgewater,bridgewater.kimberly@endo.com,Par/Endo Pharma,"Dec 23, 2024 16:09:58",approved,"Jan 14, 2025 13:00:56","Jan 14, 2025 13:47:35",47,Yes,P1134 and P1107,United States,

No,Jenny,Jenny,Jackson,jyjc@novonordisk.com,Novo Nordisk,"Dec 24, 2024 14:00:21",approved,--,--,--,--,1029,,
Yes,Amanda Gardner,Amanda,Gardner,amanda.gardner@cms.hhs.gov,CMS,"Dec 26, 2024 09:10:46",approved,"Jan 14, 2025 13:00:46","Jan 14, 2025 13:47:32",47,Yes,JanMnfrCal,United States,
No,Caitlin,Caitlin,Leach,caitlin.leach@cms.hhs.gov,CMS,"Dec 26, 2024 10:03:40",approved,--,--,--,--,P1234,,
No,Lisa,Lisa,McCabe,lmccabe@lifepittsburgh.org,LIFE Pittsburgh,"Dec 26, 2024 11:56:12",denied,--,--,--,--,H3918,,
No,Viet,Viet,Nguyen,nguyent@careoregon.org,CareOregon,"Dec 26, 2024 12:03:35",denied,--,--,--,--,H5859,,
No,Jayson,Jayson,Slotnik,jayson@ealthpolicystrategiesllc.com,Ono,"Dec 26, 2024 15:05:33",approved,--,--,--,--,1847,,
Yes,Yvonne Donahue,Yvonne,Donahue,ydonahue@Hikma.com,Hikma Pharmaceuticals USA Inc.,"Dec 27, 2024 09:50:23",approved,"Jan 14, 2025 13:02:15","Jan 14, 2025 13:47:35",46,Yes,P1242,United States,
Yes,David Nieradka,David,Nieradka,david.nieradka@boehringer-ingelheim.com,Boehringer,"Dec 27, 2024 10:45:18",approved,"Jan 14, 2025 13:00:56","Jan 14, 2025 13:47:29",47,Yes,1125,United States,
Yes,Melissa Morley,Melissa,Morley,mmorley@rti.org,RTI International,"Dec 27, 2024 16:15:43",approved,"Jan 14, 2025 13:01:07","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
Yes,Melissa Morley,Melissa,Morley,mmorley@rti.org,,,,"Jan 14, 2025 13:01:07","Jan 14, 2025 13:21:06",20,Yes,,United States
Yes,Melissa Morley,Melissa,Morley,mmorley@rti.org,,,,"Jan 14, 2025 13:03:58","Jan 14, 2025 13:47:34",44,Yes,,United States
No,Keren,Keren,Kravec,keren.kravec@cms.hhs.gov,CMS,"Dec 31, 2024 11:19:15",approved,--,--,--,--,JanMnfrCall,,
Yes,John Kautter,John,Kautter,jkautter@rti.org,RTI International,"Jan 02, 2025 07:19:51",approved,"Jan 14, 2025 13:01:27","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
Yes,Laurie Hinnant,Laurie,Hinnant,hinnant@rti.org,RTI International ,"Jan 02, 2025 09:12:17",approved,"Jan 14, 2025 13:00:58","Jan 14, 2025 13:47:34",47,Yes,DAPS,United States,
Yes,Xinqi Li,Xinqi,Li,xli@rti.org,RTI International,"Jan 02, 2025 09:24:19",approved,"Jan 14, 2025 13:00:51","Jan 14, 2025 13:47:34",47,Yes,GS-00F-354CA 75FCMC24F0128,United States,
Yes,Nila Sathe,Nila,Sathe,nsathe@rti.org,RTI,"Jan 02, 2025 09:27:49",approved,"Jan 14, 2025 13:00:41","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCal,United States,
No,Kaitlin,Kaitlin,Hunter,kaitlin.hunter@cms.hhs.gov,CMS,"Jan 02, 2025 10:02:04",approved,--,--,--,--,JanMnfrCall,,
Yes,Lindzee Smith,Lindzee,Smith,LBSMITH@RTI.ORG,RTI International,"Jan 02, 2025 10:17:48",approved,"Jan 14, 2025 13:02:15","Jan 14, 2025 13:47:34",46,Yes,JanMnfrCall,United States,
No,katherine,katherine,Treiman,Ktreiman@rti.org,RTI International,"Jan 02, 2025 10:33:41",approved,--,--,--,--,DAPS,,

Yes,Marisa Aurora,Marisa,Aurora,maurora@rti.org,RTI,"Jan 02, 2025 10:38:49",approved,"Jan 14, 2025 13:01:04","Jan 14, 2025 13:47:32",47,Yes,JanMnfrCall,United States,
Yes,Rebecca Cole,Rebecca,Cole,rebecca.cole@cms.hhs.gov,CMS,"Jan 02, 2025 10:48:59",approved,"Jan 14, 2025 13:00:39","Jan 14, 2025 13:47:32",47,Yes,JanMnfrCall,United States,
Yes,Elizabeth Mannick,Elizabeth,Mannick,emannick@rti.org,RTI International,"Jan 02, 2025 12:44:44",approved,"Jan 14, 2025 13:00:32","Jan 14, 2025 13:47:34",48,Yes,GS-00F-354CA:75FCMC24F0128,United States,
Yes,Ekemini Isaiah,Ekemini,Isaiah,ekemini.isaiah@daiichisankyo.com,Daiichi Sankyo,"Jan 02, 2025 13:58:50",approved,"Jan 14, 2025 13:37:31","Jan 14, 2025 13:37:48",1,Yes,P1062,United States,
Yes,Ekemini Isaiah,Ekemini,Isaiah,ekemini.isaiah@daiichisankyo.com,,,,"Jan 14, 2025 13:38:06","Jan 14, 2025 13:47:34",10,Yes,,United States
No,Stephen,Stephen,Demeo,steve.demeo@alcon.com,Alcon,"Jan 02, 2025 14:28:59",approved,---,--,--,--,P1442,,
No,Andrew,Andrew,Jennings,andrew.jennings2@cms.hhs.gov,CMS,"Jan 02, 2025 14:32:35",approved,---,---,---,---,JanMnfrCall,,
No,Giorgio,Giorgio,Parise,g.parise@pharming.com,Pharming Healthcare,"Jan 02, 2025 15:58:13",approved,--,--,--,--,P1549,,
Yes,Kathleen Black,Kathleen,Black,kathleen.black@pfizer.com,Pfizer,"Jan 02, 2025 16:57:49",approved,"Jan 14, 2025 13:01:05","Jan 14, 2025 13:47:34",47,Yes,P1107,United States,
No,Benjamin,Benjamin,Silver,bcsilver@rti.org,RTI International,"Jan 02, 2025 20:07:26",approved,--,--,--,--,JanMnfrCall,,
No,Tracy,Tracy,Jones,jonestl@summacare.com,SummaCare,"Jan 03, 2025 06:48:21",denied,---,---,--,--,JAIX,,
Yes,Cathy Zhang,Cathy,Zhang,qzhang@sklsi.com,"SK Life Science, Inc. ","Jan 03, 2025 10:15:31",approved,"Jan 14, 2025 13:00:48","Jan 14, 2025 13:47:08",47,Yes,P1542,United States,
Yes,Tina Li,Tina,Li,ting.li@cms.hhs.gov,CMS,"Jan 03, 2025 11:42:08",approved,"Jan 14, 2025 13:00:53","Jan 14, 2025 13:47:32",47,Yes,L8Q7,United States,
Yes,Ying Wang,Ying,Wang,Ywang97@its.jnj.com,Johnson & Johnson,"Jan 03, 2025 11:51:35",approved,"Jan 14, 2025 13:31:12","Jan 14, 2025 13:47:34",17,Yes,XP1135,United States,
Yes,Ying Wang,Ying,Wang,Ywang97@its.jnj.com,,,,"Jan 14, 2025 13:01:47","Jan 14, 2025 13:47:34",46,Yes,,United States
Yes,Ying Wang,Ying,Wang,Ywang97@its.jnj.com,,,,"Jan 14, 2025 13:02:53","Jan 14, 2025 13:47:35",45,Yes,,United States
Yes,Ying Wang,Ying,Wang,Ywang97@its.jnj.com,,,,"Jan 14, 2025 13:05:03","Jan 14, 2025 13:47:33",43,Yes,,United States
Yes,Ying Wang,Ying,Wang,Ywang97@its.jnj.com,,,,"Jan 14, 2025 13:08:03","Jan 14, 2025 13:47:32",40,Yes,,United States
Yes,Ying Wang,Ying,Wang,Ywang97@its.jnj.com,,,,"Jan 14, 2025 13:18:14","Jan 14, 2025 13:47:34",30,Yes,,United States

Yes,Els Houtsmuller,Els,Houtsmuller,ehoutsmuller@rti.org,RTI International,"Jan 03, 2025 12:45:05",approved,"Jan 14, 2025 13:00:44","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
Yes,Lauren Anderson,Lauren,Anderson,lauren_anderson@accord-healthcare.com,"Accord BioPharma, Inc.","Jan 06, 2025 09:13:19",approved,"Jan 14, 2025 13:01:23","Jan 14, 2025 13:47:34",47,Yes,P1921,United States,
Yes,Kalyn Bilger,Kalyn,Bilger,kalyn.bilger@cms.hhs.gov,CMS,"Jan 06, 2025 09:37:27",approved,"Jan 14, 2025 13:00:49","Jan 14, 2025 13:47:32",47,Yes,JanMnfrCall,United States,
Yes,Mark Seris,Mark,Seris,mark_seris@merck.com,Merck Sharp & Dohme LLC,"Jan 06, 2025 09:39:13",approved,"Jan 14, 2025 13:00:55","Jan 14, 2025 13:30:31",30,Yes,P1004,United States,
Yes,Mark Seris,Mark,Seris,mark_seris@merck.com,,,,"Jan 14, 2025 13:00:56","Jan 14, 2025 13:47:35",47,Yes,,United States
No,Elizabeth,Elizabeth,Eakle,elizabeth.eakle@cms.hhs.gov,CMS,"Jan 06, 2025 09:52:49",approved,--,--,--,--,JanMfrCall,,
No,Lynne,Lynne,Kuhn,lynne.kuhn@bayer.com,Bayer,"Jan 06, 2025 10:03:49",approved,--,--,--,--,P1161,,
No,Kristen,Kristen,Roig,Kroig@dcca.com,DCCA,"Jan 06, 2025 10:42:05",approved,--,--,--,--,JanMnfrCall,,
Yes,Bethany Habeeb,Bethany,Habeeb,bethany.habeeb@cms.hhs.gov,CMS,"Jan 06, 2025 10:47:57",approved,"Jan 14, 2025 13:00:44","Jan 14, 2025 13:47:33",47,Yes,JanMnfrCall,United States,
Yes,Michelle Brunsen,Michelle,Brunsen,mbrunsen@telligen.com,Telligen,"Jan 06, 2025 12:50:06",approved,"Jan 14, 2025 13:01:01","Jan 14, 2025 13:47:28",47,Yes,JanMnfrCall,United States,
Yes,Joanna Haize-Clawson,Joanna,Haize-Clawson,jhaize-clawson@telligen.com,Telligen,"Jan 06, 2025 12:50:19",approved,"Jan 14, 2025 13:00:59","Jan 14, 2025 13:47:35",47,Yes,Telligen,United States,
Yes,Haley Shipman,Haley,Shipman,hshipman@telligen.com,Telligen,"Jan 06, 2025 12:57:33",approved,"Jan 14, 2025 13:42:47","Jan 14, 2025 13:47:34",5,Yes,JanMnfrCall,United States,
Yes,Natasha Edwards,Natasha,Edwards,natasha.edwards@abbvie.com,AbbVie,"Jan 06, 2025 14:14:39",approved,"Jan 14, 2025 13:00:37","Jan 14, 2025 13:47:34",47,Yes,P1003,United States,
Yes,Will Kim,Will ,Kim,will.kim@abbvie.com,AbbVie,"Jan 06, 2025 14:23:59",approved,"Jan 14, 2025 13:05:33","Jan 14, 2025 13:47:35",43,Yes,P1003,United States,
No,Sarah,Sarah,Arnold,sarnold@rti.org,RTI International,"Jan 06, 2025 15:09:19",approved,--,--,--,--,JanMnfrCall,,
No,Carmen,Carmen,Carrero,carmen.carrero@bayer.com,Bayer HealthCare,"Jan 06, 2025 15:10:08",approved,--,--,--,--,P1161,,
Yes,Jonathan Stegall,Jonathan,Stegall,jonathan.stegall@a1msolutions.com,A1M Solutions,"Jan 06, 2025 15:24:49",approved,"Jan 14, 2025 13:00:33","Jan 14, 2025 13:26:51",27,Yes,JanMnfrCall,United States,
Yes,Jonathan Stegall,Jonathan,Stegall,jonathan.stegall@a1msolutions.com,,,,"Jan 14, 2025 13:00:58","Jan 14, 2025 13:47:34",47,Yes,,United States

No,Estenieau,Estenieau,Jean,ejean@trhc.com,Anewhealth,"Jan 06, 2025 16:12:35",approved,--,--,--,--,N/A,,
Yes,Eric Aman,Eric,Aman,eaman@healthfirst.org,Healthfirst,"Jan 06, 2025 16:13:50",approved,"Jan 14, 2025 13:00:59","Jan 14, 2025 13:24:55",24,Yes,H3359,United States,
No,Abe,Abe,Fernandez,abe.fernandez@ipsen.com,Ipsen,"Jan 06, 2025 16:17:12",approved,--,--,--,--,P1079,,
No,Amanda,Amanda,Bartelme,Amanda_Bartelme@eisai.com,"Eisai, Inc.","Jan 06, 2025 16:17:40",approved,---,---,---,---,P1143,,
No,Michael,Michael,Christiano,mchristiano@ardelyx.com,Ardelyx Inc.,"Jan 06, 2025 16:19:51",approved,--,--,--,--,73154,,
Yes,Alexis Sharabaika,Alexis,Sharabaika,asharabaika@kalvista.com,"KalVista Pharmaceuticals, Inc.","Jan 06, 2025 16:25:28",approved,"Jan 14, 2025 13:08:55","Jan 14, 2025 13:47:34",39,Yes,P1787,United States,
Yes,Brittany Farris,Brittany,Farris,Brittany.Farris@maynepharma.com,Mayne Pharma,"Jan 06, 2025 16:28:48",approved,"Jan 14, 2025 13:02:18","Jan 14, 2025 13:24:04",22,Yes,P1487,United States,
No,Jennifer,Jennifer,Uldrich,jsaundersuldrich@chsbuffalo.org,Catholic Health LIFE,"Jan 06, 2025 16:29:12",approved,--,--,--,--,H1518,,
Yes,Andrew Chiao,Andrew,Chiao,andrew.chiao@cms.hhs.gov,CMS/HHS,"Jan 06, 2025 16:32:43",approved,"Jan 14, 2025 13:00:36","Jan 14, 2025 13:47:34",47,Yes,n/a,United States,
No,David,David,Schmotzer,David.Schmotzer@trinity-health.org,Trinity Health PACE,"Jan 06, 2025 16:32:47",denied,--,--,--,--,"H3919, H6551 and H3493",,
Yes,Emily Ahrens,Emily,Ahrens,emily.ahrens@sanofi.com,Sanofi,"Jan 06, 2025 16:34:41",approved,"Jan 14, 2025 13:13:23","Jan 14, 2025 13:47:19",34,Yes,P1024,United States,
Yes,Juanita Moxley,Juanita,Moxley,JuanitaM@amphastar.com,Amphastar,"Jan 06, 2025 16:35:52",approved,"Jan 14, 2025 13:02:20","Jan 14, 2025 13:33:45",32,Yes,P1915,United States,
No,Ivan,Ivan,Tosques,itosques@corium.com,Corium,"Jan 06, 2025 16:37:52",approved,--,--,--,--,P1593,,
No,Sung Mi,Sung Mi,Kil,skil@healthfirst.org,Healthfirst,"Jan 06, 2025 16:38:40",approved,--,--,---,---,H3359,,
No,Jill,Jill,Farkas,jfarkas@amgen.com,Amgen,"Jan 06, 2025 16:39:26",approved,--,--,--,--,P1177,,
Yes,Robert Felsch,Robert,Felsch,rfelsch@ardelyx.com,Ardelyx,"Jan 06, 2025 16:41:03",approved,"Jan 14, 2025 13:00:54","Jan 14, 2025 13:47:08",47,Yes,P1539,United States,
Yes,Diane Bass,Diane,Bass,diane.bass@mnk.com,Mallinckrodt ,"Jan 06, 2025 16:44:45",approved,"Jan 14, 2025 13:04:38","Jan 14, 2025 13:47:31",43,Yes,P1213,United States,
Yes,Diane Bass,Diane,Bass,diane.bass@mnk.com,,,,"Jan 14, 2025 13:14:42","Jan 14, 2025 13:47:34",33,Yes,,United States
No,Katherine,Katherine,Lewis,katherine.lewis@chs-corp.com,CommuniCare and West Virginia Senior Advantage,"Jan 06, 2025 16:46:34",denied,---,---,---,---,H3727 and H9153,,

Yes,Karen Agama,Karen,Agama,karen.agama@merz.com,"Merz Pharmaceuticals, LLC","Jan 06, 2025 16:48:04",approved,"Jan 14, 2025 13:00:45","Jan 14, 2025 13:47:34",47,Yes,P1085,United States,
No,Elena,Elena,Moraitis,emorai02@amgen.com,Horizon Therapeutics (Amgen),"Jan 06, 2025 16:48:33",approved,--,--,--,--,MXN0,,
No,Ilham,Ilham,Batar,batar@usc.edu,USC,"Jan 06, 2025 16:49:45",denied,--,--,--,--,m,,
Yes,Scott Williams,Scott,Williams,Scott.Williams@mnk.com,Mallinckrodt Pharmaceuticals Inc.,"Jan 06, 2025 16:56:41",approved,"Jan 14, 2025 13:00:38","Jan 14, 2025 13:47:32",47,Yes,P1213,United States,
Yes,Gayla Norwood,Gayla,Norwood,Gayla.Norwood@mnk.com,Mallinckrodt ARD LLC,"Jan 06, 2025 16:59:16",approved,"Jan 14, 2025 13:01:41","Jan 14, 2025 13:47:34",46,Yes,P1213,United States,
Yes,Bret Hughes,Bret,Hughes,bhughes@incyte.com,Incyte Corporation,"Jan 06, 2025 17:03:24",approved,"Jan 14, 2025 13:25:20","Jan 14, 2025 13:47:35",23,Yes,P1233,United States,
No,Kurt,Kurt,Lenhart,kurt.lenhart@apex4health.com,Memorial Hermann,"Jan 06, 2025 17:06:15",denied,--,--,--,--,H7115,,
No,Angie,Angie,Thomas,angie.thomas@mnk.com,SpecGx LLC,"Jan 06, 2025 17:07:11",approved,--,--,--,--,P1258,,
No,Stacey,Stacey,Hammond,slhammond2@chp.org,Capital Health Plan,"Jan 06, 2025 17:07:40",denied,--,--,--,--,H5938,,
Yes,Ekta Ghimire,Ekta,Ghimire,eghimire@acumenllc.com,Acumen LLC (DCCA subcontractor on the MTF DM project),"Jan 06, 2025 17:13:50",approved,"Jan 14, 2025 13:02:15","Jan 14, 2025 13:08:55",7,Yes,G7IB,United States,
Yes,Ekta Ghimire,Ekta,Ghimire,eghimire@acumenllc.com,,,,"Jan 14, 2025 13:08:50","Jan 14, 2025 13:14:09",6,Yes,,United States
No,Pamela,Pamela,Cleveland,pcleveland@mednet.ucla.edu,New Century Health Plan,"Jan 06, 2025 17:23:03",denied,--,--,--,--,H4647,,
No,Alison,Alison,hanson,alison.t.hanson@healthpartners.com,HealthPartners,"Jan 06, 2025 17:28:10",denied,--,--,--,--,h4882,,
No,Kaelyn,Kaelyn,Buck,kaelyn.buck@regeneron.com,Regeneron Pharmaceuticals,"Jan 06, 2025 17:36:09",approved,--,--,--,--,P1202,,
No,Brendan,Brendan,Bertsch,brbe@genmab.com,Genmab,"Jan 06, 2025 17:42:59",approved,--,--,--,--,BBXI,,
Yes,Nataliya Averyanova,Nataliya,Averyanova,naveryanova@emblemhealth.com,EmblemHealth,"Jan 06, 2025 18:07:19",approved,"Jan 14, 2025 13:06:08","Jan 14, 2025 13:47:34",42,Yes,H3330,United States,
Yes,Laura Blair,Laura,Blair,lblair@riparian.com,Riparian,"Jan 06, 2025 18:12:07",approved,"Jan 14, 2025 13:02:02","Jan 14, 2025 13:47:34",46,Yes,P1740,United States,
No,Michele,Michele,Kimak,michele.kimak@tevapharm.com,Teva,"Jan 06, 2025 18:23:24",approved,--,--,--,--,P1006,,
Yes,Mary Martin,Mary,Martin,mary.martin@ucb.com,"UCB, Inc","Jan 06, 2025 18:43:48",approved,"Jan 14, 2025 13:00:48","Jan 14, 2025 13:10:55",11,Yes,MRXU,United States,

Yes,Mary Martin,Mary,Martin,mary.martin@ucb.com,,,,"Jan 14, 2025 13:09:20","Jan 14, 2025 13:30:33",22,Yes,,United States
No,Erin,Erin,Darling,erin.darling@merck.com,Merck,"Jan 06, 2025 19:09:41",approved,--,--,--,--,P1004,,
Yes,Kathy Kulkarni,Kathy,Kulkarni,katk@ascendispharma.com,Ascendis Pharma,"Jan 06, 2025 22:37:38",approved,"Jan 14, 2025 13:00:34","Jan 14, 2025 13:23:41",24,Yes,P1615,United States,
No,Shauna,Shauna,Horn,shauna.horn@sutterhealth.org,Sutter SeniorCare PACE,"Jan 07, 2025 00:14:26",denied,--,--,--,--,H5406,,
No,Mike,Mike,Pica,mike.pica@cloverhealth.com,Clover Health,"Jan 07, 2025 06:39:14",denied,--,--,--,--,H5141,,
Yes,Michelle Callies-Virshup,Michelle,Callies-Virshup,michelle.calliesvirshup@cms.hhs.gov,CMS-MDRNG,"Jan 07, 2025 07:35:56",approved,"Jan 14, 2025 13:00:40","Jan 14, 2025 13:47:35",47,Yes,JanMnfrCall,United States,
No,Scott ,Scott ,Dudley,scott.dudley@medmutual.com,Medical Mutual of Ohio,"Jan 07, 2025 07:58:35",denied,--,--,--,--,H4497,,
No,Kim,Kim,Timpson,kim.timpson@oha.ri.gov,"Office of Healthy Aging, States Area on Aging","Jan 07, 2025 08:06:11",approved,--,--,--,--,SPAP manager,,
No,Lisa,Lisa,Caprara,lisa.caprara@pillarrx.com,PillarRx Consulting,"Jan 07, 2025 08:11:34",approved,--,--,--,--,H2400,,
Yes,Karie Miller,Karie,Miller,karie.miller@mnk.com,Mallinckrodt Pharmaceuticals,"Jan 07, 2025 08:23:34",approved,"Jan 14, 2025 13:00:32","Jan 14, 2025 13:47:34",48,Yes,P1213,United States,
Yes,Sleth Ibanez,Sleth,Ibanez,sibanez@careplus-hp.com,"CarePlus Health Plans, Inc.","Jan 07, 2025 08:54:32",approved,"Jan 14, 2025 13:05:59","Jan 14, 2025 13:27:45",22,Yes,H1019,United States,
No,Cre'shawna,Cre'shawna,White,whitec@piedmonthealth.org,Piedmont Health SeniorCare,"Jan 07, 2025 09:22:40",denied,--,--,--,--,H9266,,
No,Tiffany,Tiffany,Zeronski,tiffany.zeronski@novartis.com,Novartis Pharmaceuticals,"Jan 07, 2025 09:29:47",approved,--,--,--,--,P1008,,
No,David,David,Rossi,david.rossi@pharmpix.com,PharmPix,"Jan 07, 2025 09:33:36",denied,--,--,--,--,RX7M,,
No,Abner ,Abner ,Martinez,amartine@apotexcorp.com,Apotex Corp. ,"Jan 07, 2025 09:36:53",approved,--,--,--,--,M73X,,
No,Dylan,Dylan,Schreiner,dylan.schreiner@bakertilly.com,Orphalan Limited,"Jan 07, 2025 10:02:22",approved,--,--,--,--,NSSU,,
No,Logan,Logan,Houchens,logan.houchens@Pharmpix.com,PharmPix,"Jan 07, 2025 10:03:29",denied,--,--,--,--,HXRF,,
Yes,Alicia Graziano,Alicia,Graziano,alicia.graziano@pharma.com,Purdue Pharma L.P.,"Jan 07, 2025 10:27:15",approved,"Jan 14, 2025 13:00:36","Jan 14, 2025 13:47:34",47,Yes,P1180,United States,
Yes,Tim Byrne,Tim,Byrne,timothy.byrne@jazzpharma.com,Jazz,"Jan 07, 2025 10:39:33",approved,"Jan 14, 2025 13:00:32","Jan 14, 2025 13:47:34",48,Yes,P1087,United States,

Yes,Mark Borkovec,Mark,Borkovec,mark.borkovec@alk.net,"ALK-Abello, Inc","Jan 07, 2025 10:50:29",approved,"Jan 14, 2025 13:00:43","Jan 14, 2025 13:47:33",47,Yes,BWHN,United States,
Yes,Christian Gingerella,Christian,Gingerella,christian.gingerella@millicentpharma.com,Millicent U.S. Inc.,"Jan 07, 2025 10:58:08",approved,"Jan 14, 2025 13:02:55","Jan 14, 2025 13:42:30",40,Yes,72495,United States,
Yes,Christine August,Christine,August,caugust@xerispharma.com,"Xeris Pharmaceuticals, Inc.","Jan 07, 2025 11:36:49",approved,"Jan 14, 2025 13:00:39","Jan 14, 2025 13:47:34",47,Yes,P1619,United States,
Yes,Christine August,Christine,August,caugust@xerispharma.com,,,,"Jan 14, 2025 13:00:55","Jan 14, 2025 13:47:33",47,Yes,,United States
Yes,Christine August,Christine,August,caugust@xerispharma.com,,,,"Jan 14, 2025 13:02:00","Jan 14, 2025 13:47:33",46,Yes,,United States
Yes,Amanda Teeple,Amanda ,Teeple,ateeple@its.jnj.com,Johnson & Johnson,"Jan 07, 2025 11:49:07",approved,"Jan 14, 2025 13:01:01","Jan 14, 2025 13:47:34",47,Yes,"P1135, P1243",United States,
Yes,Athena Colucci,Athena,Colucci,acolucci@theratech.com,Theratechnologies,"Jan 07, 2025 11:57:32",approved,"Jan 14, 2025 13:04:47","Jan 14, 2025 13:47:30",43,Yes,CV91,United States,
No,Katherine,Katherine,Lauver,Katherine_dangelo@merck.com,Merck,"Jan 07, 2025 12:10:02",approved,--,--,--,--,p1004,,
Yes,Venkateswara Yarlagadda,Venkateswara,Yarlagadda,Venkateswara.yarlagadda1@cms.hhs.gov,CMS,"Jan 07, 2025 12:28:10",approved,"Jan 14, 2025 13:00:41","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
No,Sandy,Sandy,Fischer,sfischer@ingenus.com,"Ingenus Pharmaceuticals, LLC","Jan 07, 2025 12:31:08",approved,--,--,--,--,p1327,,
No,Allison,Allison,Carboni,acarboni@xerispharma.com,Xeris Pharmaceuticals,"Jan 07, 2025 12:51:44",approved,--,--,--,--,P1619,,
No,Amy,Amy,Howes,amy.howes@us.sumitomo-pharma.com,Sumitomo Pharma America,"Jan 07, 2025 12:53:09",approved,--,--,--,--,P1086,,
Yes,lou schroeter,lou,schroeter,lou.schroeter@boehringer-ingelheim.com,Boehringer Ingelheim,"Jan 07, 2025 13:01:26",approved,"Jan 14, 2025 13:00:50","Jan 14, 2025 13:47:09",47,Yes,Boehringer Ingelheim,United States,
No,Kristal,Kristal,Godfrey,Kristal.Godfrey@cms.hhs.gov,CMS,"Jan 07, 2025 13:06:01",approved,--,--,--,--,JanMnfrCall,,
Yes,Kevin Savio,Kevin,Savio,ksavio@legacypharmainc.com,Legacy Pharma,"Jan 07, 2025 13:07:14",approved,"Jan 14, 2025 13:01:34","Jan 14, 2025 13:47:18",46,Yes,XP1853,United States,
No,Angel ,Angel ,Palacios,apalacios@elpasohealth.com,EPH ,"Jan 07, 2025 13:38:28",denied,--,--,--,--,H3407,,
Yes,Mark Matthews,Mark,Matthews,mark.matthews@cms.hhs.gov,CMS,"Jan 07, 2025 14:07:23",approved,"Jan 14, 2025 13:02:51","Jan 14, 2025 13:47:34",45,Yes,JanMnfrCall,United States,

Yes,Stephen Smith,Stephen,Smith,stephen.smith2@pfizer.com,Pfizer,"Jan 07, 2025 14:18:45",approved,"Jan 14, 2025 13:00:40","Jan 14, 2025 13:47:35",47,Yes,P1077,United States,
No,Paul,Paul,Lakomski,plakomski@emblemhealth.com,EmblemHealth,"Jan 07, 2025 14:38:12",denied,---,---,---,---,H3330,,
No,Wendy,Wendy,Dean,wendydean@sbcglobal.net,ConnectiCare,"Jan 07, 2025 14:43:53",denied,--,--,--,--,H3528,,
No,Jeffrey,Jeffrey,Miller,jeffrey.miller@lannett.com,Lannett Company Inc.,"Jan 07, 2025 15:34:39",approved,---,---,---,---,P1280,,
Yes,Ben Sloan,Ben,Sloan,bsloan@redhillus.com,"RedHill Biopharma, Inc.","Jan 07, 2025 15:45:03",approved,"Jan 14, 2025 13:00:51","Jan 14, 2025 13:47:34",47,Yes,P1560,United States,
No,Dee,Dee,Conner,deeannac@bluestemks.org,Bluestem PACE,"Jan 07, 2025 16:15:34",denied,--,--,--,--,H9438,,
No,Jordana,Jordana,Koja-Volk,Jordana.koja-volk@medimpact.com,MG Insurance Company,"Jan 07, 2025 16:43:21",denied,--,--,--,--,S3285,,
Yes,Forest Grefe,Forest,Grefe,fgrefe@xerispharma.com,"Xeris BioPharma Holdings, Inc.","Jan 07, 2025 17:31:46",approved,"Jan 14, 2025 13:00:56","Jan 14, 2025 13:47:34",47,Yes,P1619,United States,
No,Dalia ,Dalia ,Mahmoud ,dalia.mahmoud@abbvie.com,Abbvie,"Jan 07, 2025 17:42:31",approved,---,---,---,---,P-1003,,
No,Heidi,Heidi,Robbins,heidi.rubin@emdserono.com,"EMD Serono, Inc.","Jan 07, 2025 19:00:48",approved,--,--,--,--,hrrobbins,,
No,Izzy,Izzy,Perez,israel.perez@astrazeneca.com,AstraZeneca,"Jan 08, 2025 08:35:03",approved,---,---,---,---,N/A,,
Yes,Andrew Pearlman,Andrew,Pearlman,apearlman@rti.org,RTI International,"Jan 08, 2025 10:14:11",approved,"Jan 14, 2025 13:01:01","Jan 14, 2025 13:47:35",47,Yes,JanMnfrCall,United States,
Yes,Carolyn Williams,Carolyn,Williams,carolyn.williams@a1msolutions.com,A1M Solutions,"Jan 08, 2025 11:49:04",approved,"Jan 14, 2025 13:00:51","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
Yes,Christina Reid,Christina,Reid,christina.reid@emdserono.com,EMD Serono,"Jan 08, 2025 12:00:22",approved,"Jan 14, 2025 13:01:44","Jan 14, 2025 13:47:33",46,Yes,XP1065,United States,
Yes,Linda Lynch,Linda,Lynch,linda.lynch@emdserono.com,EMD Serono,"Jan 08, 2025 12:04:24",approved,"Jan 14, 2025 13:00:34","Jan 14, 2025 13:22:09",22,Yes,XP1065,United States,
Yes,Linda Lynch,Linda,Lynch,linda.lynch@emdserono.com,,,,"Jan 14, 2025 13:25:52","Jan 14, 2025 13:47:34",22,Yes,,United States
Yes,Rhonda Sorrell,Rhonda,Sorrell,rhonda.s.sorrell@gsk.com,GlaxoSmithKline,"Jan 08, 2025 13:14:37",approved,"Jan 14, 2025 13:00:48","Jan 14, 2025 13:47:34",47,Yes,IXP1101,United States,
Yes,Jacqueline Roche,Jacqueline,Roche,jroche8@its.jnj.com,Johnson and Johnson ,"Jan 08, 2025 13:25:06",approved,"Jan 14, 2025 13:00:48","Jan 14, 2025 13:47:32",47,Yes,XP1135,United States,
No,Jill,Jill,Page,jill.page@alcon.com,Alcon,"Jan 08, 2025 14:09:25",approved,--,--,--,--,P1442,,

Yes,Maporn Lertsuridej,Maporn,Lertsuridej,mlertsuridej@acumenllc.com,Acumen LLC,"Jan 08, 2025 15:14:50",approved,"Jan 14, 2025 13:05:51","Jan 14, 2025 13:47:13",42,Yes,JanMnfrCall,United States,
No,Yana,Yana,Khassanov,yana.khassanov@elderservehealth.org,RiverSpring Health Plans,"Jan 08, 2025 15:50:08",denied,--,--,--,--,H6776,,
No,Wendy,Wendy,Dean,wdean@connecticare.com,ConnectiCare,"Jan 08, 2025 16:23:45",denied,--,--,--,--,H3528,,
No,Abra,Abra,Bron,abra.bron@abbvie.com,AbbVie,"Jan 08, 2025 18:54:28",approved,--,--,--,--,P1003,,
No,Gregory,Gregory,Pope,gpope@rti.org,RTI International,"Jan 09, 2025 11:37:31",approved,--,--,--,--,0000,,
No,Susan,Susan,McDougal,susan@ferapharma.com,Fera Pharmaceuticals,"Jan 09, 2025 12:05:09",approved,--,--,--,--,P1834,,
Yes,George Handlin,George,Handlin,ghandlin@its.jnj.com,Johnson & Johnson,"Jan 09, 2025 12:17:21",approved,"Jan 14, 2025 13:00:50","Jan 14, 2025 13:47:35",47,Yes,XP1135,United States,
Yes,erika george,erika,george,erika.george@bridgebio.com,BridgeBio,"Jan 09, 2025 12:26:58",approved,"Jan 14, 2025 13:01:02","Jan 14, 2025 13:47:34",47,Yes,82228,United States,
Yes,Jeff Letizia,Jeff,Letizia,jeff.letizia@astellas.com,Astellas Pharma US Inc,"Jan 09, 2025 12:30:51",approved,"Jan 14, 2025 13:02:15","Jan 14, 2025 13:47:24",46,Yes,LYG7,United States,
Yes,Jessica Roth,Jessica,Roth,jessica.roth@takeda.com,Takeda,"Jan 09, 2025 14:43:48",approved,"Jan 14, 2025 13:01:23","Jan 14, 2025 13:47:32",47,Yes,P1116,United States,
Yes,Priya Elumalai,Priya,Elumalai,Priya_Elumalai@eisai.com,Eisai Inc.,"Jan 09, 2025 14:55:48",approved,"Jan 14, 2025 13:09:27","Jan 14, 2025 13:47:34",39,Yes,P1143,United States,
No,Suzannah,Suzannah,Scanlon,suzannah.scanlon@cms.hhs.gov,CMS,"Jan 10, 2025 11:28:35",approved,--,--,--,--,99999,,
No,Alice,Alice,Lee-Martin,alice.leemartin@cms.hhs.gob,CMS,"Jan 10, 2025 11:38:43",approved,--,--,--,--,99999,,
No,Randy,Randy,Haines,haines-r@iehp.org,Inland Empire Health Plan,"Jan 10, 2025 13:00:01",denied,--,--,--,--,H8894,,
Yes,James Class,James,Class,james.class@gilead.com,Gilead Sciences,"Jan 10, 2025 13:45:51",approved,"Jan 14, 2025 13:00:50","Jan 14, 2025 13:47:34",47,Yes,P1132,United States,
Yes,Bindu Aryal,Bindu,Aryal,bindu.aryal@cms.hhs.gov,CMS,"Jan 10, 2025 13:59:38",approved,"Jan 14, 2025 13:00:36","Jan 14, 2025 13:37:47",38,Yes,99999,United States,
Yes,Lauren Paluzzi,Lauren,Paluzzi,lpaluzzi@its.jnj.com,Johnson & Johnson,"Jan 10, 2025 14:09:18",approved,"Jan 14, 2025 13:03:09","Jan 14, 2025 13:47:34",45,Yes,P1135,United States,
Yes,Amanda Huston,Amanda,Huston,amanda.huston@cms.hhs.gov,CMS,"Jan 10, 2025 15:43:42",approved,"Jan 14, 2025 13:03:16","Jan 14, 2025 13:47:34",45,Yes,JanMnfrCall,United States,

No,Vanessa,Vanessa,Turner,Vanessa.Turner@VillageCare.org,VillageCareMax,"Jan 10, 2025 15:57:24",denied,--,--,--,--,H2168,,
No,Eileen,Eileen,Eng-Liu,EileenE@villagecare.org,VilliageCare Max,"Jan 10, 2025 16:08:46",denied,--,--,--,--,H2168,,
No,Joy,Joy,Liwai,joy_liwai@hmsa.com,HMSA,"Jan 13, 2025 02:50:44",denied,--,--,--,--,H3832,,
Yes,Ryan Ricketts,Ryan,Ricketts,ryan.ricketts@pfizer.com,Pfizer,"Jan 13, 2025 11:20:22",approved,"Jan 14, 2025 13:00:55","Jan 14, 2025 13:47:34",47,Yes,P1077,United States,
Yes,Michael Yafrate,Michael,Yafrate,michael.yafrate@emdserono.com,EMD Serono,"Jan 13, 2025 11:38:37",approved,"Jan 14, 2025 13:00:54","Jan 14, 2025 13:47:34",47,Yes,YB8P/#36F79725D0011,United States,
Yes,TJ Garrigan,TJ,Garrigan,thomas.garrigan@cms.hhs.gov,CMS,"Jan 13, 2025 11:57:10",approved,"Jan 14, 2025 13:00:46","Jan 14, 2025 13:47:32",47,Yes,JanMnfrCall,United States,
Yes,Mia Barrow,Mia,Barrow,mia.barrow@a1msolutions.com,A1M Solutions,"Jan 13, 2025 12:48:24",approved,"Jan 14, 2025 13:00:54","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
Yes,Randall Ziman,Randall,Ziman,randall.ziman@a1msolutions.com,A1M Solutions,"Jan 13, 2025 12:58:53",approved,"Jan 14, 2025 13:00:55","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
Yes,James Callan,James,Callan,james.callan@a1msolutions.com,A1M Solutions,"Jan 13, 2025 12:59:33",approved,"Jan 14, 2025 13:00:49","Jan 14, 2025 13:47:34",47,Yes,JanMnfrCall,United States,
No,Victor,Victor,Swaminathan,vswami@arevapharma.com,Areva Pharmaaceuticals,"Jan 14, 2025 09:05:01",approved,--,--,--,--,P1911,,
No,Scott,Scott,Cormiea,scormiea@arevapharma.com,Areva Pharmaceuticals,"Jan 14, 2025 09:06:40",approved,--,--,--,--,P1911,,
No,Marc,Marc,Eida,marc.eida@tevapharm.com,Teva Pharmaceuticals,"Jan 14, 2025 10:02:23",pending,--,--,--,--,EMMJ,,
No,Eric,Eric,Kraus,eric.kraus@otsuka-us.com,"Otsuka America Pharmaceutical, Inc.","Jan 14, 2025 11:02:01",pending,--,--,--,--,P1027,,
No,Shekinah,Shekinah,Manigault,smanigault@mgb.org,Mass General Brigham Health Plan,"Jan 14, 2025 11:03:20",pending,--,--,--,--,H6847,,
No,David ,David ,Walker-Lečić,david.walker-lecic@a1msolutions.com,A1M Solutions,"Jan 14, 2025 11:25:58",pending,--,--,--,--,JanMnfrCall,,
No,Krista,Krista,Coleman,kcoleman@xerispharma.com,Xeris Pharmaceuticals,"Jan 14, 2025 12:50:58",pending,--,--,--,--,P1619,,
Yes,Lister Conference Room,Lister,,rooms_ioadoishs4escrrlrt-npa@phrma.onmicrosoft.com,,"Jan 14, 2025 12:57:28",approved,"Jan 14, 2025 13:00:32","Jan 14, 2025 13:47:34",48,Yes,,United States,
No,Jen,Jen,Diaz,jen_diaz@vrtx.com,Vertex Pharmaceuticals,"Jan 14, 2025 13:11:28",pending,--,--,--,--,DJ5S,,
Other Attended,
"User Name","Join Time","Leave Time","Time in Session (minutes)","Is Guest","Country/Region Name"

18453803282,"Jan 14, 2025 13:00:42","Jan 14, 2025 13:01:11",1.0,Yes,United States,
18589524593,"Jan 14, 2025 13:03:08","Jan 14, 2025 13:47:35",45.0,Yes,United States,
17032205952,"Jan 14, 2025 13:05:39","Jan 14, 2025 13:47:34",42.0,Yes,United States,
17184908925,"Jan 14, 2025 13:02:38","Jan 14, 2025 13:22:31",20.0,Yes,United States,
12022862080,"Jan 14, 2025 13:03:56","Jan 14, 2025 13:47:34",44.0,Yes,United States,
18057959067,"Jan 14, 2025 13:03:53","Jan 14, 2025 13:06:31",3.0,Yes,United States,

CMS,

In response to your email, stated below is the additional information that the agency should consider prior to any release. J&J reaffirms our recommendation stated in our November 1, 2024 response letter to redact highlighted 3rd party information without expressed approvals from these organizations.

Section 1194(e)(1) Information

Negotiation Data Elements Information Collection Request (OMB 0938-1449) (ICR)
Section: Section F - Patents, Exclusivities, and Approvals
Although specific patents are available in the public domain on the websites CMS identified, it is the collection of these specific patents that is not in the public domain. The collection of patents was variously made available for portfolio licenses to the biosimilars. Our negotiations with the biosimilars, including the patents that were made available for portfolio licenses, were confidential and subject to confidentiality agreements, confidentiality provisions in settlement agreements, and/or statutory confidentiality requirements protecting information that could be revealed by disclosure of the collection of patents. See, e.g., 42 USC §262(l)(1)(C).

Section 1194(e)(2) Information

ICR Section: Section I - Question 28 Table 3
Analysource is a subscription-based service which requires license and/or approval for access or disclosure. https://www.analysource.com/subscription-plans/ CMS must evaluate whether it needs to request its own permission for use in the disclosures and will bear the responsibility to obtain any necessary permissions for its planned use.

ICR Section: Section I - Question 30 Attachment -Figure 1
It is not clear how the information submitted was used in the basis of evaluating price. While publicly accessible online, these materials are owned by a third party and CMS must evaluate whether it needs to request its own permission for use in the disclosures and will bear the responsibility to obtain any necessary permissions for its planned use.

From: "Roche, Jacqueline [JJCUS]" <jroche8@its.jnj.com>
Sent: 7/11/2024 3:22:43 PM -0400
To: "Martin, Kristi (CMS/CM)" <Kristina.Martin@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC: "Schaeffer, John [HCSUS]" <JSchaeff@ITS.JNJ.com>; "Hancock, Rebecca [JJCUS]" <RHancoc1@ITS.JNJ.com>; "Teeple, Amanda [JRDUS]" <ateeple@ITS.JNJ.com>
BCC:
Subject: Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation

Hi, Kristi and Chris: Thank you for meeting with the &J team on June 20, 2024 to discuss the MFP effectuation. We greatly appreciate the opportunity to collaborate and share our recommendations. We strongly advocate for continued collaboration between our organizations, aiming for successful MFP effectuation through a structured cadence of regular meetings.

We have been advancing the three requests outlined during that discussion:

1. MFP Effectuation/Implementation Requirements
2. Assessing Legal authority to pre-fund the program
3. Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation

We continue to make progress on the first two items and have shared documents from our previous meeting that outline five requirements for effectuation as well as the legal basis for floating on behalf of CMS. In an upcoming communication we intend to share a deep-dive into the claim validation process. (and other metrics related to 340B verification, etc.)

To incorporate an aligned coalition perspective, we are proposing a joint session with CMS, the manufacturers affected by IPAY 2026/27 and a pharmacy stakeholder group. Our goal is to compliantly bring these stakeholders together to share industry insights, expedite decision-making, and to ensure that the final guidance represents a solution that is workable across the ecosystem players. Could you please advise when CMS would like to schedule this session? We suggest mid-August 2024 to maintain continued progress.

We look forward to your response and to continuing our productive collaboration.

Best regards,

Jackie

From: Roche, Jacqueline [JJCUS]
Sent: Friday, June 21, 2024 3:23 PM
To: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina S. (CMS/CMMI) <Christina.Ritter@cms.hhs.gov>; Coster, John (CMS/CMCS) <John.Coster@cms.hhs.gov>; michael.mccormick@cms.hhs.gov <michael.mccormick@cms.hhs.gov>; janet.brock2@cms.hhs.gov <janet.brock2@cms.hhs.gov>
Cc: Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Hancock, Rebecca [JJCUS]

<RHancoc1@ITS.JNJ.com>; Teeple, Amanda [JRDUS] <ateeple@ITS.JNJ.com>
Subject: MFP Effectuation _ J&J Follow-up

Hi, Team CMS: Thank you for the meeting yesterday with our cross-functional J&J team regarding MFP effectuation. We greatly appreciate the opportunity to collaborate and share our MFP effectuation recommendations. J&J will continue to guide this important collaboration with stakeholders since an end-to-end solution is important for supply chain integrity.

We didn't quite get there yesterday, but we strongly recommend the formulation of a governance structure among our teams to integrate our workflows, align to decisions on the critical path, etc., leading up to 1.1.26 "go live."

Attached to this email, you will find the deck we shared yesterday. The deck focused on various elements of MFP effectuation, including five critical requirements for MFP effectuation and supplementary information to support the role of these requirements. The five critical requirements we recommend are CMS Pre-funding, Mandatory use of MTF (end-to-end solution facilitating payment and data-sharing), 340 B Data transparency, 45 Day Manufacturer Process for validation and compliance processes, and Transparent Dispute/Appeals operations.

Additionally, J&J is currently developing the following:

- Legal Authority Resources (Goal: Share with CMS early next week)
- Internal business requirements for claims validation and timeline specific to MFP
- Metrics to demonstrate the scale and potential impact of reversals, duplicates, and 340B

Continued Collaboration:

- We propose the development of a collaborative governance model to jointly develop workable solutions to effectuate MFP on 1/1/26
- We recommend meeting bi-weekly to continue to jointly assess solutions

It is critical that decisions be made urgently regarding CMS Pre-Funding and the role and capabilities of the MTF to allow the appropriate infrastructure to be built for a 1/1/26 go-live. Please let us know the next available date the CMS team is available to meet to continue our conversation.

Thank you again, and we look forward to putting these next steps into action,

Have a nice weekend, my apologies I didn't have TJ's email.

Jackie

Jacqueline Roche
Head Payment and Delivery & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy WWGA&P
Mobile: (b)(6)
Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

Bristol Myers Squibb™

Dear Medicare Drug Rebate and Negotiations Group,

Bristol Myers Squibb (BMS) has received CMS' communication dated October 18, 2024, entitled "Opportunity for Pre-Disclosure Review of Manufacturer-Submitted Materials to Accompany Publication of Maximum Fair Price Explanation." We currently are preparing our response in accordance with CMS' instructions.

In the meantime, BMS respectfully requests an extension on the deadline until November 15, 2024 to allow us to conduct a thorough review of CMS' proposed redactions and to submit a comprehensive response. There is no statutory or regulatory basis for the 10-business day deadline CMS has proposed. The Inflation Reduction Act does not mandate CMS' public release of the information submitted to CMS by a manufacturer of a selected drug in the first instance, much less dictate a required timeline for manufacturers to object to disclosure of proprietary information. *See* SSA § 1195(a)(2) (requiring only that CMS publish "the explanation for the maximum fair price with respect to the factors as applied under section 1194(e)"). Agency regulations address the situation in which the Agency is *responding* to a request for information under the Freedom of Information Act, in each case providing the submitter of such information with 10 working days to object to disclosure. *See* 45 C.F.R. § 5.42(a)(2). By contrast, such regulations do not provide a timeline for objections when the agency is *proactively* releasing information. Given that CMS is not required to publish its "explanation" of the MFP until March 1, we believe submission by November 15, 2024 will give CMS adequate time to review our response.

Additionally, BMS respectively requests clarification on the scope of information CMS intends to release to the public. Specifically, CMS states that it "will release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and negotiation meetings, if applicable."

1. Regarding BMS' previously submitted data—
   a. Will any content *not* redacted be released?
   b. In what format will such content be released?

2. Regarding the "exchange of offers and counteroffers and the negotiation meetings," we understand that CMS plans to publish "the names and titles of meeting attendees and the final meeting agendas"—
   a. Please confirm that the substance of the "negotiation meetings" will not be released.
   b. What other information regarding the "exchange of offers and counteroffers," if any, will be released?

Sincerely,

Stephanie A. Dyson
SVP, US Policy & Government Affairs & Policy Communications

Bristol Myers Squibb™

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Sincerely,

Stephanie A. Dyson
SVP, US Policy & Government Affairs & Policy Communications

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An AbbVie Company

July 2, 2024

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Request for 24-hour pre-disclosure notification before any public disclosure

Dear Dr. Seshamani:

We write to remind you that AbbVie/Pharmacyclics has submitted information and data to, and engaged in discussions with, the Centers for Medicare & Medicaid Services ("CMS")—including the discussion and acceptance of a price in the June 27, 2024, meeting—under assurances of confidentiality. *See* IRA § 1193(c); CMS Guidance § 40.2.1 (citing *id.* § 40.2.2; 5 U.S.C. § 552(b)(3), (4); 18 U.S.C. § 1905). Under these same assurances, AbbVie/Pharmacyclics has submitted trade secret and confidential commercial and financial information that AbbVie/Pharmacyclics customarily and actually treats as private and that we have designated as confidential and exempt from disclosure under Exemption 4 of the FOIA, 45 C.F.R. § 5.41.

We expect that all of this information will be treated as confidential and not released or disclosed to the public. Disclosure of any of this information would result in harm to AbbVie/Pharmacyclics's business interests, including because disclosure of the "maximum fair price" ("MFP") before the statutory publication deadline—or disclosure of the "MFP" before disclosure of other IPAY 2026 MFPs—could result in public identification of confidential materials.

If CMS, the White House, or any other government entity disagrees and nevertheless intends to disclose to the public (1) the price imposed on Imbruvica before the September 1, 2024, statutory publication date, (2) any other information about the "negotiation" process involving AbbVie/Pharmacyclics, and/or (3) any data or information provided to CMS that has been marked as confidential by AbbVie/Pharmacyclics, AbbVie/Pharmacyclics hereby reiterates the request made during our meeting on June 27, 2024, that CMS provide us with at least 24-hour pre-disclosure notice as required under 45 C.F.R. § 5.42, including the specific information contained within the record that CMS, the White House, or any other government entity intends to disclose.

Sincerely,


michael staff (Jul 2, 2024 19:22 CDT)

Michael C. Staff, Vice President, Inflation Reduction Act (IRA) Product and Channel Strategies

Contains confidential commercial and trade secret information; Not subject to FOIA; Pre-disclosure notification required.

abbvie

pharmacyclics®
An AbbVie Company

July 2, 2024

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

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We expect that all of this information will be treated as confidential and not released or disclosed to the public. Disclosure of any of this information would result in harm to AbbVie/Pharmacyclics's business interests, including because disclosure of the "maximum fair price" ("MFP") before the statutory publication deadline—or disclosure of the "MFP" before disclosure of other IPAY 2026 MFPs—could result in public identification of confidential materials.

If CMS, the White House, or any other government entity disagrees and nevertheless intends to disclose to the public (1) the price imposed on Imbruvica before the September 1, 2024, statutory publication date, (2) any other information about the "negotiation" process involving AbbVie/Pharmacyclics, and/or (3) any data or information provided to CMS that has been marked as confidential by AbbVie/Pharmacyclics, AbbVie/Pharmacyclics hereby reiterates the request made during our meeting on June 27, 2024, that CMS provide us with at least 24-hour pre-disclosure notice as required under 45 C.F.R. § 5.42, including the specific information contained within the record that CMS, the White House, or any other government entity intends to disclose.

Sincerely,


michael staff (Jul 2, 2024 19:22 CDT)

Michael C. Staff, Vice President, Inflation Reduction Act (IRA) Product and Channel Strategies

Contains confidential commercial and trade secret information; Not subject to FOIA; Pre-disclosure notification required.

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-15-12
Baltimore, Maryland 21244-1850

Center for Medicare

June 26, 2024

Michael Staff
Pharmacyclics LLC

VIA EMAIL: michael.staff@abbvie.com; iris.gafnikane@abbvie.com; hayden.kennedy@abbvie.com; johanna.corbin@abbvie.com; paul.j.aynilian@abbvie.com; dina.kasper@abbvie.com

Dear Mr. Staff:

Thank you for your response to CMS' preliminary agenda and submission of the document titled Supportive Content for June 27, 2024 Meeting, shared with CMS on June 20, 2024, regarding the ongoing negotiation for a maximum fair price for Imbruvica (hereafter the "Selected Drug").

On February 1, 2024, CMS sent an initial offer to Pharmacyclics LLC, which included CMS' initial offer price per 30-day equivalent supply of $7,622.00 for the Selected Drug and a concise justification of the initial offer. Consistent with section 1194(b)(2)(B) of the Social Security Act (the Act) and section 60.4.1 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, the information contained in the concise justification provided Pharmacyclics LLC with information on the range of evidence and other information considered pursuant to section 1194(e) of the Act that CMS found compelling during the development of the initial offer for the Selected Drug.

We have appreciated the opportunity to further discuss our views on the section 1194(e) factors, as well as Pharmacyclics LLC's views and additional considerations, during the two negotiation meetings to date on April 26 and May 31, 2024. During the most recent meeting on May 31, 2024, Pharmacyclics LLC representatives expressly stated that the discussions during the first two meetings were productive and that there was a particularly good exchange during the May 31, 2024 meeting; we shared that assessment. In that meeting on May 31, 2024, CMS presented a revised offer to Pharmacyclics of $8,398.00 per 30-day equivalent supply for the Selected Drug. CMS' revised offer demonstrates CMS' ongoing commitment to negotiating to reach an agreement with Pharmacyclics LLC on a maximum fair price for the Selected Drug, and it reflects that CMS has listened to and considered Pharmacyclics LLC's perspectives expressed in the course of negotiations. Pharmacyclics LLC representatives declined CMS' revised offer during the meeting, but stated that they appreciated CMS presenting a revised offer and wanted to have further dialogue with CMS. Because Pharmacyclics LLC declined CMS' revised offer in the meeting, CMS did not populate an Addendum to reflect it.

We look forward to a productive third meeting on June 27, 2024 where Pharmacyclics LLC can raise the items identified in its response to CMS' preliminary agenda and in the materials it submitted in support of

the meeting in continued pursuit of the goal of reaching agreement on a maximum fair price for the Selected Drug.

Thank you,

Medicare Drug Rebate and Negotiations Group

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-15-12
Baltimore, Maryland 21244-1850

Center for Medicare

[DATE]

Michael Staff

Pharmacyclics LLC

VIA EMAIL: michael.staff@abbvie.com; martha.skup@abbvie.com

Dear Mr. Staff,

Thank you for your email, dated July 2, 2024, confirming your signature on the Medicare Drug Price Negotiation Agreement Negotiated Maximum Fair Price Addendum for Imbruvica (hereafter the "Selected Drug"), and your letter to Dr. Seshamani attached to the same; we are responding on her behalf.

Section 60.2 of the Medicare Drug Price Negotiation Program: Revised Guidance ("Revised Guidance") provides a description of the methodology used to calculate a ceiling price. On December 1, 2023, CMS sent information on the calculation of the ceiling and the computation of how CMS will apply an agreed-upon single MFP across dosage forms and strengths for the Selected Drug to Pharmacyclics, LLC, consistent with the suggestion of error process descripted in section 40.5. Pharmacyclics LLC submitted a suggestion of error on December 19, 2023, asking about observed differences in data inputs across the ceiling and application of MFP files. CMS responded to the suggestion of error on January 18, 2024, confirming that these differences were a result of different inclusion criteria for the two calculations, as described in the Revised Guidance, and not a calculation or computation error.

On February 1, 2024, CMS sent an initial offer to Pharmacyclics LLC, which included CMS' initial offer price per 30-day equivalent supply of $7,622.00 for the Selected Drug and a concise justification of the initial offer. Consistent with section 1194(b)(2)(B) of the Social Security Act (the Act) and section 60.4.1 of the Revised Guidance, the information contained in the concise justification provided Pharmacyclics LLC with information on the range of evidence and other information considered pursuant to section 1194(e) of the Act that CMS found compelling during the development of the initial offer for the Selected Drug.

We have appreciated the opportunity to further discuss our views on the section 1194(e) factors, as well as Pharmacyclics LLC's views and additional considerations, during the three negotiation meetings on April 26, May 31, and June 27, 2024. In the meeting on June 27, 2024, CMS presented a revised offer to Pharmacyclics of $9,153.00 per 30-day equivalent supply for the Selected Drug. In that meeting, Pharmacyclics LLC then proposed a price per 30-day equivalent supply of $9,319.00, which CMS accepted, and both parties subsequently signed a Negotiation Program Agreement Addendum agreeing to this price. CMS' revised offer and CMS' subsequent acceptance of Pharmacyclics LLC's revised counteroffer both demonstrated CMS' commitment to negotiating to reach an agreement with Pharmacyclics LLC on a maximum fair price for the Selected Drug, and these actions reflected that CMS listened to and considered Pharmacyclics LLC's perspectives expressed in the course of negotiations,

including related to topics such as research and development costs, patents and exclusivities and newly available comparative clinical evidence that were discussed in the third meeting.

The Revised Guidance does not establish compliance obligations or penalty structures for parties other than the Primary Manufacturer of the Selected Drug. Additionally, Section 40.6 of the Revised Guidance provides detailed information regarding mechanisms available to the Primary Manufacturer to opt out of the Negotiation Program without penalty. During the negotiation meeting held on May 31, 2024, CMS provided information about the policy as described in sections 40 and 40.6 as specific to the Selected Drug and Pharmacyclics LLC. CMS notes that in the negotiation meeting held on June 27, 2024, Pharmacyclics LLC did not ask any follow-up questions or otherwise seek to clarify the information that CMS had provided during the May 31, 2024 meeting.

We have appreciated the productive exchange of information with Pharmacyclics LLC throughout the Negotiation Process, which has resulted in an MFP agreed to in association with the final negotiation meeting, reflecting a robust and good-faith negotiation.

Thank you,

Medicare Drug Rebate and Negotiations Group

Citations - Question 29: Comparative Effectiveness in Specific Populations Response

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29. Data on file, REF-98688. Ghosh. AbbVie Inc. 2023.
30. Data on file, REF-98677. Crawford S. AbbVie Inc. 2023.

From:	Jennifer L Alley <jennalley@lilly.com>
Sent:	1/7/2025 4:14:44 PM -0500
To:	"Becerra, Xavier (OS/IOS)" <Xavier.Becerra@hhs.gov>; "Brooks-LaSure, Chiquita (CMS/OA)" <Chiquita.Brooks-LaSure@cms.hhs.gov>; "Seshamani, Meena (CMS/OA)" <Meena.Seshamani@cms.hhs.gov>
CC:	
BCC:	
Subject:	Ensuring Insulin Availability in the United States
Attachments:	image001.png; Humalog CMS Letter - 1.7.2025.pdf

Secretary Becerra, Administrator Brooks-LaSure, and Deputy Administrator Seshamani:

Attached is a letter to your attention regarding insulin availability in the United States. As referenced in the letter, we would welcome the opportunity to meet with you or your staff to discuss this issue further.

Best regards,

Dave Ricks

Dave Ricks *(he/him)*

Chair and Chief Executive Officer

ricks_david@lilly.comÂÂÂÂÂÂ

Eli Lilly and Company

Lilly Corporate Center, Indianapolis, IN 4ÂÂÂÂ6285 USA

www.lilly.com

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop WB-06-05
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

July 24, 2024

VIA EMAIL: antonr@amgen.com; mbusch@amgen.com; jfarkas@amgen.com; ygawlik@amgen.com

RE: Section 1194(e)(1) Data Submission for Enbrel®

Dear Immunex Corporation:

The Centers for Medicare & Medicaid Services (CMS) requests that Immunex Corporation resubmit certain data previously submitted under Section 1194(e)(1) of the Social Security Act (the Act) in the CMS Health Plan Management System (CMS HPMS). CMS uses these data in the methodology to apply an agreed-upon maximum fair price (MFP) across dosage forms and strengths for your Selected Drug for initial price applicability year (IPAY) 2026.

Following CMS' previous inquiry related to units reported in Section G (Market Data and Revenue and Sales Volume Data), on December 14, 2023, Immunex Corporation updated the National Council of Prescription Drug Programs Billing Unit Standards (NCPDP BUS) for all NDC-11s listed in Section G, Question 16 from each (EA) to milliliter (ML), except for NDC 58406-0425-34, which you maintained has a NCPDP BUS of EA. CMS has determined that this correction of the submitted NCPDP BUS rendered inaccurate the associated WAC unit price and WAC total unit volume data reported in Section G question 16 because the WAC data for these NDC-11s reflect the uncorrected NCPDP BUS. In accordance with Section 40.2.3 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (Revised Guidance), CMS requests that Immunex Corporation resubmit WAC unit price and WAC total unit volume data for these NDC-11s that reflect the corrected NCPDP BUS.

We have re-opened your access to CMS HPMS so that you can make these updates. **Within five (5) business days of receipt of this letter, please correct your previously reported WAC unit price and WAC total unit volume data and make any necessary revisions in Section G, Question 16 for each NDC-11 listed in that section in CMS HPMS to ensure the reported WAC prices and WAC total unit volumes are complete and accurate**. Once you have updated the information in Section G, you must complete Section H (Certification of Submission for Primary Manufacturers) to complete your resubmission. **Upon resubmission, respond to this email to alert CMS that you have completed this process.**

In accordance with Section 1196(a)(2) of the Act and Section 60.5 of the Revised Guidance, CMS uses the manufacturer-submitted quarterly WAC per unit and unit volume data in the methodology to apply the single MFP across different dosage forms and strengths of the Selected Drug. As such, it is critical that Immunex Corporation timely update the WAC unit price and WAC total unit volume

for each NDC-11 listed in Section G, Question 16 in CMS HPMS to reflect the corrected NCPDP BUS. Once you have corrected WAC unit prices and WAC total unit volumes and recertified your submission, CMS will use your corrected data to update the document previously provided to you on December 28, 2023 that demonstrates how an agreed-upon MFP would apply across dosage forms and strengths of Enbrel for IPAY 2026. CMS will timely share the updated document with Immunex Corporation. Please note that this request for corrective action and the subsequent update to MFP application across dosage forms and strengths of Enbrel for IPAY 2026 to incorporate corrected manufacturer-submitted data do not affect any timelines or requirements of the Negotiation Program, including but not limited to the date by which the Primary Manufacturer must accept or reject CMS' "Notification of Final Maximum Fair Price Offer" dated July 15, 2024.

Please send any questions about this notice to IRArebateandnegotiation@cms.hhs.gov.

Regards,
Medicare Drug Rebate and Negotiations Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop WB-06-05
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

July 24, 2024

VIA EMAIL: antonr@amgen.com; mbusch@amgen.com; jfarkas@amgen.com; ygawlik@amgen.com

RE: Section 1194(e)(1) Data Submission for Enbrel®

Dear Immunex Corporation:

The Centers for Medicare & Medicaid Services (CMS) requests that Immunex Corporation resubmit certain data previously submitted under Section 1194(e)(1) of the Social Security Act (the Act) in the CMS Health Plan Management System (CMS HPMS). CMS uses these data in the methodology to apply an agreed-upon maximum fair price (MFP) across dosage forms and strengths for your Selected Drug for initial price applicability year (IPAY) 2026.

Following CMS' previous inquiry related to units reported in Section G (Market Data and Revenue and Sales Volume Data), on December 14, 2023, Immunex Corporation updated the National Council of Prescription Drug Programs Billing Unit Standards (NCPDP BUS) for all NDC-11s listed in Section G, Question 16 from each (EA) to milliliter (ML), except for NDC 58406-0425-34, which you maintained has a NCPDP BUS of EA. CMS has determined that this correction of the submitted NCPDP BUS rendered inaccurate the associated WAC unit price and WAC total unit volume data reported in Section G question 16 because the WAC data for these NDC-11s reflect the uncorrected NCPDP BUS. In accordance with Section 40.2.3 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (Revised Guidance), CMS requests that Immunex Corporation resubmit WAC unit price and WAC total unit volume data for these NDC-11s that reflect the corrected NCPDP BUS.

We have re-opened your access to CMS HPMS so that you can make these updates. **Within five (5) business days of receipt of this letter, please correct your previously reported WAC unit price and WAC total unit volume data and make any necessary revisions in Section G, Question 16 for each NDC-11 listed in that section in CMS HPMS to ensure the reported WAC prices and WAC total unit volumes are complete and accurate**. Once you have updated the information in Section G, you must complete Section H (Certification of Submission for Primary Manufacturers) to complete your resubmission. **Upon resubmission, respond to this email to alert CMS that you have completed this process.**

In accordance with Section 1196(a)(2) of the Act and Section 60.5 of the Revised Guidance, CMS uses the manufacturer-submitted quarterly WAC per unit and unit volume data in the methodology to apply the single MFP across different dosage forms and strengths of the Selected Drug. As such, it is critical that Immunex Corporation timely update the WAC unit price and WAC total unit volume

for each NDC-11 listed in Section G, Question 16 in CMS HPMS to reflect the corrected NCPDP BUS. Once you have corrected WAC unit prices and WAC total unit volumes and recertified your submission, CMS will use your corrected data to update the document previously provided to you on December 28, 2023 that demonstrates how an agreed-upon MFP would apply across dosage forms and strengths of Enbrel for IPAY 2026. CMS will timely share the updated document with Immunex Corporation. Please note that this request for corrective action and the subsequent update to MFP application across dosage forms and strengths of Enbrel for IPAY 2026 to incorporate corrected manufacturer-submitted data do not affect any timelines or requirements of the Negotiation Program, including but not limited to the date by which the Primary Manufacturer must accept or reject CMS' "Notification of Final Maximum Fair Price Offer" dated July 15, 2024.

Please send any questions about this notice to IRArebateandnegotiation@cms.hhs.gov.

Regards,
Medicare Drug Rebate and Negotiations Group

Subject: Update– MFP Application Across Dosage Forms and Strengths for IPAY 2026

Dear AstraZeneca AB,

In accordance with section 1194(c) of the Social Security Act ("the Act") and section 60.2 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("Revised Guidance"), CMS calculated the ceiling for Farxiga. Further, in accordance with section 1196(a)(2) of the Act and section 60.5 of the Revised Guidance, CMS calculated how any agreed-upon maximum fair price (MFP) would apply across dosage forms and strengths of Farxiga. On December 1st, 2023, CMS sent an email to AstraZeneca AB with a link to the results of these calculations for Farxiga and a suggestion of error form. The email was sent from the (IRARebateandNegotiation@cms.hhs.gov) email box to ADD NAMES.

CMS identified five new NDC-11s of Farxiga in January and February of 2024. The new NDC-11s of Farxiga identified were 50090-7056-00, 50090-7057-00, 66993-0456-30, 66993-0457-30, and 63629-3253-01. On April 1, 2024, CMS sent a notice requesting that AstraZeneca confirm whether each NDC-11 listed above was 1) marketed or controlled by the Primary Manufacturer or a Secondary Manufacturer, or marketed or controlled by a manufacturer that is not the Primary Manufacturer or a Secondary Manufacturer and 2) a sample package. On April 5th, 2024, AstraZeneca AB responded that only two of these five NDC-11s (66993-0456-30 and 66993-0457-30) are marketed/controlled by the Primary Manufacturer or a Secondary Manufacturer and not sample packages. In the same email correspondence, AstraZeneca AB notified CMS of two additional NDC-11s of Farxiga that are marketed/controlled by the Primary Manufacturer or a Secondary Manufacturer and not sample packages (00310-6205-90 and 00310-6210-90).

CMS has determined that any agreed-upon MFP should apply to all seven newly identified NDC-11s of Farxiga. CMS determined any agreed-upon MFP should apply to NDC-11s 50090-7056-00, 50090-7057-00, and 63629-3253-01 because they are NDC-11s of authorized generics based on information found in the NDC Directory and NDC SPL Data Element file (MARKETINGCATEGORYNAME=NDA AUTHORIZED GENERIC). Your response that these are not marketed or controlled by the Primary Manufacturer or Secondary Manufacturer does not align with the definition of Secondary Manufacturer as described in Section 40 of the Revised Guidance: "A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meet these criteria."

CMS has updated the document that details how any agreed-upon MFP would apply across dosage forms and strengths of Farxiga by adding these seven NDC-11s (50090-7056-00, 50090-7057-00, 66993-0456-30, 66993-0457-30, 63629-3253-01, 00310-6205-90, and 00310-6210-90). CMS added these seven NDC-11s to the "MFP NDC Calculator" worksheet in the "Manu_MFP_DFS_IPAY2026_Farxiga_041524.xlsx" Excel file. The updated "Manu_MFP_DFS_IPAY2026_Farxiga_041524.xlsx" Excel file has been uploaded to Box (ADD LINK) and is ready for download. If you are unable to access the link to the revised document, please respond to this email to let us know how you would like to receive them.

As described in section 40.2 of the Revised Guidance, the Primary Manufacturer has an ongoing obligation to timely report any changes to the list of NDC-11s of the selected drug to ensure the list of NDC-11s remains complete and accurate.

Thank you,

CMS Medicare Drug Rebate and Negotiations Group

From:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent:	3/1/2024 3:00:59 PM -0500
To:	"Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>
CC:	
BCC:	
Subject:	FW: FW: Imbruvica "Counteroffer" Supplemental Letter
Attachments:	image001.gif; Counteroffer Supplement_3.1.24 - signed.pdf

Out of Scope

From: Kennedy, Hayden R <hayden.kennedy@abbvie.com>
Sent: Friday, March 1, 2024 2:51 PM
To: Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>; CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Cc: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Heider, Daniel (CMS/CM) <daniel.heider@cms.hhs.gov>
Subject: Imbruvica "Counteroffer" Supplemental Letter

Dr. Seshamani,

Attached please find a cover letter to accompany AbbVie/Pharmacyclics' "counteroffer" response with respect to Imbruvica.

Sincerely,

Hayden Kennedy

HAYDEN R. KENNEDY

Vice President

Global Policy & U.S. Access Strategies
Government Affairs

1 North Waukegan Road

AP34

North Chicago, IL 60064

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PRIVILEGED & CONFIDENTIAL DRAFT

CONTAINS ASTRAZENECA CONFIDENTIAL AND PROPRIETARY INFORMATION EXEMPT FROM RELEASE UNDER FOIA

December 9, 2024

Medicare Drug Rebate and Negotiations Group
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Farxiga (Dapagliflozin)
Supplement to Response Regarding Pre-Disclosure Review of Manufacturer-Submitted Materials to Accompany Publication of Maximum Fair Price Explanation

Dear Medicare Drug Rebate and Negotiations Group,

This letter responds to the Centers for Medicare & Medicaid Services' ("CMS's") November 27, 2024, e-mail ("CMS E-mail") regarding pre-disclosure review of information that CMS intends to publish with its maximum fair price ("MFP") explanation for Farxiga (Dapagliflozin). The CMS E-mail requested that AstraZeneca AB ("AstraZeneca" or the "Company") "supplement its response" and provide additional information for certain of the Company's requested redactions.

For the reasons explained in our November 18, 2024, letter to CMS, AstraZeneca continues to object to the publication of its Negotiation Data Elements Information Collection Request ("ICR") submission for Farxiga (the "ICR Submission"), in whole or in part. The IRA does not authorize nor require CMS to publish manufacturers' ICR submissions or other information related to their negotiation meetings with CMS.[1] AstraZeneca's entire ICR Submission is protected from public disclosure under federal law, including the Inflation Reduction Act ("IRA"),[2] the Freedom of Information Act ("FOIA"),[3] and the Trade Secrets Act,[4] as well as under CMS policy and guidance. The totality of AstraZeneca's ICR Submission reflects the Company's confidential and proprietary business strategy with respect to its negotiations with CMS, which the Company has made significant efforts to protect from public disclosure. If, despite AstraZeneca's strong objections, CMS intends to release portions of the information contained in the ICR Submission, AstraZeneca continues to object to the disclosure of any part of its ICR Submission that contains

[1] Social Security Act § 1195(a)(2).
[2] Social Security Act § 1193(c).
[3] 5 U.S.C. § 552.
[4] 18 U.S.C. § 1905.

confidential, competitively-sensitive, proprietary and/or trade secret information, which under no circumstance would AstraZeneca release to the general public or make accessible to competitors. This information must be withheld under applicable law and not used for any purpose other than administering the Negotiation Program.

In Sections I and II, we respond to CMS's requests for additional information regarding AstraZeneca's redaction requests in the event that CMS publishes portions of the ICR Submission despite the Company's objections. We have also attached a Revised Exhibit 2,[5] and new Exhibits 4[6] and 5.[7]

I. Section 1194(e)(1) Information

The CMS Letter solicits additional information to support AstraZeneca's request that CMS redact certain information related to Farxiga's patents. AstraZeneca maintains that the full compilation of Farxiga's patent information is protected under the IRA, FOIA Exemption 4, and other federal laws, because it reflects the highly confidential, proprietary internal business strategies and analysis of AstraZeneca. In addition, we restate our strong opposition to CMS disclosing patents that have never been listed in the Orange Book as associated with Farxiga. Our responses to CMS's requests are below. We also have attached a Revised Exhibit 2, which reflects our updated redaction requests in Section F of the ICR Submission.

Negotiation Data Elemengts Information Collection Request (OMB 0938-1449) (ICR) Section:
Section F - Patents, Exclusivities, and Approvals

- **Specific Area of Concern:** Patents (Expired and Non-Expired) and Patent Applications
- **Description:** On pages 10 and 11 of the review material, AstraZeneca AB requested to redact information regarding patents no. 6414126, no. 6936590, and no. 9198925.
- **CMS Observation:** CMS has noted AstraZeneca AB's request for redaction of the stated patents in Section F. CMS has observed that these patents have previously been published in the FDA Orange Book, as recent as the 42nd Annual Edition. CMS has observed that these patents have been publicly associated with the selected drug. We are seeking to better understand AstraZeneca AB's request to redact this information.
- **AstraZeneca Response:** AstraZeneca restates its position that the ICR Submission should not be disclosed either in whole or in part because it reflects AstraZeneca's confidential and proprietary business strategy with respect to its negotiations with CMS. Notwithstanding with above, AstraZeneca rescinds its request that CMS specifically redact the patents no. 6414126, no. 6936590, and no. 9198925 from pages 10 and 11 of Revised Exhibit 2.

[5] Exhibit 2 contains updated redactions to the Section 1194(e)(1) submission.
[6] Exhibit 4 contains updated redactions to Figure 1, in response to Question 28 of the ICR.
[7] Exhibit 5 contains updated redactions to Figure 4, in response to Question 28 of the ICR.

ICR Section: Section F - Patents, Exclusivities, and Approvals

- **Specific Area of Concern:** Patents (Expired and Non-Expired) and Patent Applications
- **Description:** On pages 11 and 12 of the review material, AstraZeneca AB requested to redact information regarding patent applications no. 2020/0078382 and no. 2021/0260083.
- **CMS Observation:** CMS has noted AstraZeneca AB's request for redaction of the stated patents in Section F. CMS has observed that these patents have been published on the FDA Orange Book database, which can be accessed here. CMS has observed that these patents have been publicly associated with the selected drug. We are seeking to better understand AstraZeneca AB's request to redact this information.

  AstraZeneca Response: AstraZeneca restates its position that the ICR Submission should not be disclosed either in whole or in part because it reflects AstraZeneca's confidential and proprietary business strategy with respect to its negotiations with CMS. Notwithstanding the above, AstraZeneca rescinds its request that CMS specifically redact patent application no. 2020/0078382 and no. 2021/0260083 from pages 11 and 12 of Revised Exhibit 2.

ICR Section: Section F - Patents, Exclusivities, and Approvals

- **Specific Area of Concern:** Patents (Expired and Non-Expired) and Patent Applications
- **Description:** On pages 11 and 12 of the proposed redacted E1 data submission, AstraZeneca AB requested to redact seven bullet points related to patents that CMS has proposed to not redact and are in the Orange Book, including patent numbers: 6936590, 9198925, 7851502, 8221786, 8716251, 8501698, 6515117, 7919598, 2020/0078382, and 2021/0260083.
- **CMS Observation:** CMS has noted AstraZeneca AB's request to redact information regarding patents submitted under Section F. CMS has observed that the patents no. 2020/0078382, and no. 2021/0260083 are now active. For these patents and the other patents noted above, CMS has observed this information to be published in previous editions of the FDA Orange Book as well as the current FDA database found here. CMS has observed that these patents have been publicly associated with the selected drug. We are seeking to better understand AstraZeneca AB's request to redact this information.
- **AstraZeneca Response:** AstraZeneca restates its position that the ICR Submission should not be disclosed either in whole or in part because it reflects AstraZeneca's confidential and proprietary business strategy with respect to its negotiations with CMS. Notwithstanding the above, AstraZeneca rescinds its request that CMS specifically redact the bullet points related to the patents that CMS has identified above. For clarity, and as reflected in Revised Exhibit 2, AstraZeneca maintains its request that CMS redact the remaining bullet points, which reflect AstraZeneca's characterization of patents that are not listed in the Orange Book. These characterizations are not public and are highly confidential to the Company.

II. Section 1194(e)(2) Information

ICR Section: Section I – *Question 28 Attachment*

- **Specific Area of Concern**: Figures 1 and 4
- **Description**: AstraZeneca AB requested to redact the following text at the bottom of page 1 of Figure 1 and at the bottom of page 1 of Figure 4: "Sources: Farxiga (dapagliflozin) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, 2023." Additionally, in the Excel file titled "Exhibit 1 – PreDisclosure Review – Redaction Chart_Final_11-18-2024" provided by AstraZeneca AB, AstraZeneca AB listed sources requested for redaction in Question 28 Figure 1 and in Question 28 Figure 4, which are included in No. 57 and No. 61 of the Excel file, respectively, and do not include the source information for "Farxiga" as a listed source.
- **CMS Observation**: CMS has observed that while AstraZeneca AB requested redaction of all sources in the highlighted text in Figures 1 and 4 (which includes "Fargixa"); AstraZeneca AB did not include "Sources: Farxiga (dapagliflozin) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, 2023" as a requested redaction in No. 57 and in No. 61 of the Excel file. We are seeking to better understand the different redaction requests between the Figures 1 and 4 and the Excel file.
- **AstraZeneca Response:** AstraZeneca restates its position that the ICR Submission should not be disclosed either in whole or in part because it reflects AstraZeneca's confidential and proprietary business strategy with respect to its negotiations with CMS. Notwithstanding the above, AstraZeneca rescinds its request that CMS specifically redact Farxiga's package insert as a source for Figures 1 and 4. We have attached a revised version of AstraZeneca's requested redactions to ICR Submission Section I, Question 28, attached as Exhibit 4 (Figure 1) and Exhibit 5 (Figure 4). AstraZeneca maintains its position that the Company's other requested redactions in Figures 1 and 4 reflect the Company's confidential, competitively sensitive information that AstraZeneca specifically developed for use with payor customers, including CMS, and for confidential customer negotiations. Additionally, the other requested redactions in Figures 1 and 4 reflect AstraZeneca's confidential, competitively sensitive, and proprietary business strategies.

* * * * *

AstraZeneca respectfully insists that CMS treat this letter and the documents and information AstraZeneca is producing with this letter as highly confidential and exempt from disclosure under FOIA, and not disclose it or its contents outside of CMS or use it for any purpose other than administering the Negotiation Program. AstraZeneca appreciates CMS holding the Company's proprietary and confidential information in strict confidence and the agency's prompt notification to AstraZeneca of any adverse determination or request for disclosure in accordance with all applicable federal law so that the Company may take all necessary actions to protect and keep confidential its proprietary information. If we can be of further assistance in this matter or provide additional information, please feel free to contact Rod Lauzon.

Congress of the United States

Washington, DC 20515

July 8, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and
Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Call for CMS to Not Impose DIR Fees on Drugs in the Inflation Reduction Act That Are Assessed a Maximum Fair Price (MFP)

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

As the Center for Medicare and Medicaid Services (CMS) works to implement provisions of the Inflation Reduction Act (P.L. 117-169), the undersigned ask that CMS ensure that plans and pharmacy benefit managers (PBMs) do not charge direct and indirect remuneration (DIR) fees to pharmacies for negotiated drugs. Implementation of IRA requirements must not result in additional financial pressure and loss for our nation's pharmacies. The IRA is clear that pharmacies are not to be reimbursed below the "maximum fair price" (MFP) for negotiated drugs. We are concerned that pharmacies will be reimbursed below the MFP, especially if DIR fees are assessed on these drugs. Additionally, pharmacy reimbursement should be reasonable and cover acquisition cost plus margin plus include a commensurate professional dispensing fee (currently, PBMs pay retail pharmacies dispensing fees far below the actual cost to dispense, as low as $0). Long-term care (LTC) pharmacies and specialty pharmacies should be safeguarded from being disproportionately affected, given LTC and specialty pharmacies' higher dispensing costs compared to the retail setting, based on CMS's ten criteria for LTC pharmacy and the patient service requirements for specialty. Additionally, CMS should not require any reporting of pharmacy's acquisition cost given anti-competitive concerns.

Pharmacies are already facing significant cash flow concerns in Medicare Part D, and failing to establish protections against DIR fees on MFP drugs or to ensure appropriate pharmacy dispensing fees and prompt payment to pharmacies (as required by the IRA) would exacerbate those concerns. According to a recent survey[1] by the National Community Pharmacists Association, 32 percent of all respondents say they are considering closing their doors in 2024 because of the cash crunch in Medicare. **Ninety-three percent say they may drop out of Medicare Part D in 2025 if this year's experience continues, which would decimate patient access across the country, especially for senior citizens.** More than half of all respondents say Medicare Part D prescriptions account for 40 percent or more of their business. According to the survey, 99 percent of respondents say their prescription reimbursements have gone down since CMS's *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* Final Rule[2] took effect on January 1, 2024.

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[1] National Community Pharmacists Association, *Local Pharmacies on the Brink, New Survey Reveals* (February 27, 2024) (Online at https://ncpa.org/newsroom/news-releases/2024/02/27/local-pharmacies-brink-new-survey-reveals).

[2] Federal Register, *Section 1198(b)(1)(C), p. 36* (May 9, 2022) (Online at https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and).

The Inflation Reduction Act created an exception to non-interference in the Part D clause in Section 1860D–11(i) of the Social Security Act.[3] **We request that CMS use this exception to establish a price structure for the Medicare Drug Price Negotiation Program, specifically a financially viable model of pharmacy reimbursement including but not limited to a maximum fair price that accounts for margin on the ingredient cost of the drug, plus a required and economically viable professional dispensing fee, and that Part D plans and PBMs cannot pay pharmacies at less than that maximum fair price. Further, we request that CMS ensure that PBMs cannot assess pharmacy DIR fees on MFP drugs.**

Pharmacy "deserts" are proliferating in the country, especially in some of the areas where our country's most socially vulnerable populations reside.[4] In 2023, there were over 300 independent pharmacy *net* closures — in other words, *every day* patients have one fewer independent pharmacy from which to choose. Additionally, there are approximately 2,200 fewer retail pharmacies than there were four years ago—an overall 4 percent decrease in pharmacy choices for patients—and that pattern of pharmacy closures is increasing. Based on the most recent data through February 29, 2024, independent pharmacy net closures continue at approximately one store per day. **We urge CMS to act to preserve all pharmacy access for seniors by addressing the financial pressures that risk further eliminating access to the pharmacy of their choice.**

We thank CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer solutions.

Sincerely,

Raja Krishnamoorthi
Member of Congress

Donald G. Davis
Member of Congress

Vicente Gonzalez
Member of Congress

[3] United States Code, *42 U.S.C. §1395w–111(i)(3)*, "[the Secretary] may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of subchapter XI [the Medicare Drug Price Negotiation Program provisions]" (Online at https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter7-subchapter18-partD-subpart2&saved=%7CKHRpdGxlOjOyIHNlY3Rpb246MTM5NXctMTE1IGVkaXRpb246cHJlbGltKQ%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim).

[4] University of Pittsburgh, *Mapping U.S. Pharmacy Closures* (Accessed June 13, 2024) (Online at https://storymaps.arcgis.com/stories/21620f1e07c14d7f81adc4503faaf51e).

Johnson&Johnson

November 1, 2024

VIA Electronic Filing – IRARebateandNegotiation@cms.hhs.gov

RE: Response to CMS on Pre-disclosure

Dear Administrator Seshamani:

On behalf of Johnson and Johnson (J&J) we submit the following adjustments in accordance with your letter dated October 18, 2024 for a pre-disclosure review by the manufacturer for materials received by CMS for XARELTO and STELARA.

Our submission includes the redactions required under FOIA exemptions (#4) which are highlighted in the documents with provided explanation. These redactions are required to prevent our trade secrets and confidential financial, business, copyright, and patent information from being disclosed inappropriately to the market. CMS should be aware that some 3rd party tables and charts enclosed are protected under licensing, copyright laws and regulations. CMS should redact these images or contact the publisher for proper approvals prior to dissemination.

In addition, J&J submitted all clinical documentation to CMS as part of the scientific exchange required by the IRA's drug price "negotiation" in the selection of our drugs. The evidence provided was mandated under CMS requirements, is not promotional in nature, and proper qualifications under FDA requirements should be considered prior to publication.

J&J also advises CMS to utilize precautions for avoiding communication that can be deemed as medical advice or prescribing recommendations. There is a considerable non-medical switching risk for beneficiaries that could impact treatment if our confidential information is improperly disclosed and/or misinterpreted.

CMS has outlined in guidance the purpose for providing an explanation on the greatest impact in determining the MFPs and include a discussion of the other section 1194(e) data, as applicable. Section 1195(a)(2) requires publication of the explanation of how the negotiation factors under section 1194(e) were applied to determine the MFP and does not permit price offers and counteroffers to be publicized. These offers should be redacted without disclosure. Like other negotiations between commercial entities and government agencies such as the VA, under FOIA Exemption 4 this information is private and confidentially held by manufacturers.

J&J recognizes the law requires CMS to publish their explanation of the "MFP" for XARELTO and STELARA no later than March 1, 2025. We urge CMS to provide manufacturers advance notice of this explanation and supporting materials prior to public release. If CMS disagrees with any of the additional redactions J&J proposed, we request CMS provide adequate notice to J&J so we can take appropriate action.

Sincerely,

John Schaeffer
Sr. Director, Strategy and Operations, Emerging Government Policy
Johnson & Johnson Innovation Medicine Strategic Customer Group

From: "Coster, John (CMS/CM)" <John.Coster@cms.hhs.gov>
Sent: 6/28/2024 7:58:40 AM -0400
To: "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC:
BCC:
Subject: FW: FW: MFP Effectuation Memo_ CMS Authority
Attachments: Final MFP Effectuation Memo.pdf

Out of Scope

From: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>
Sent: Thursday, June 27, 2024 3:19 PM
To: Garrigan, Thomas (CMS/CM) <thomas.garrigan@cms.hhs.gov>; Coster, John (CMS/CM) <John.Coster@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>
Subject: Fwd: MFP Effectuation Memo_ CMS Authority

Out of Scope

From: Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>
Sent: Thursday, June 27, 2024 3:15:11 PM
To: Martin, Kristi (CMS/CM) <Kristina.Martin@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Cc: McNamara, Stefanie [JJCUS] <SMcNama7@its.jnj.com>; Hancock, Rebecca [JJCUS] <RHancoc1@ITS.JNJ.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Teeple, Amanda [JRDUS] <ateeple@ITS.JNJ.com>
Subject: MFP Effectuation Memo_ CMS Authority

Hi, Kristi and Chris: Attached is a memo prepared for J&J and CMS regarding CMS' authority in establishing an effectuation model that includes a pre-fund. I'm also introducing my J&J GC colleague, Stefanie McNamara.

Help me with the CMS preferred timing to discuss and/or if it would be helpful for us to send this memo directly to OGC.

We are available to discuss and walk both the CMS and HHS/OGC teams through the memo.

Thank you,

Jackie & Stefanie

Kind Regards,

Jacqueline Roche

Head Payment and Delivery & Global Policy Institute

Johnson & Johnson Worldwide Government Affairs & Policy WWGA&P

Mobile: (b)(6)

Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

From:	"Hunter, Kaitlin (CMS/CM)" <Kaitlin.Hunter@cms.hhs.gov>
Sent:	1/15/2025 3:15:07 PM -0500
To:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Coster, John (CMS/CM)" <John.Coster@cms.hhs.gov>
CC:	"Weiss, Rachel (CMS/CM)" <rachel.weiss@cms.hhs.gov>
BCC:	
Subject:	FW: FW: January 14 Manufacturer Call Question Log
Attachments:	image007.png; image008.png; image009.png; image010.png; image011.png; image012.png; Jan 2025 Monthly Manufacturer Call_Live Question Log.docx; Jan 14 Mnfr Call - Attendee Report.csv; Jan 14 Mnfr Call - Q&A Report.csv

Out of Scope

From: Devon Lara <DLARA@mitre.org>
Sent: Wednesday, January 15, 2025 3:13 PM
To: Weiss, Rachel (CMS/CM) <rachel.weiss@cms.hhs.gov>; Hunter, Kaitlin (CMS/CM) <Kaitlin.Hunter@cms.hhs.gov>; Eakle, Elizabeth (CMS/CM) <Elizabeth.Eakle@cms.hhs.gov>
Cc: Kelsey Shields <KSHIELDS@mitre.org>; Emily McPherson <EMCPHERSON@mitre.org>; Margo R Green <mrosner@mitre.org>; Lauren Benbow <LBENBOW@mitre.org>; Tommy Larson <tlarson@mitre.org>; Shannon Knight <SKKNIGHT@mitre.org>; Daya, Anjali (CMS/CM) <anjali.daya@cms.hhs.gov>; Godfrey, Kristal (CMS/CM) <Kristal.Godfrey@cms.hhs.gov>; Abigail Painchaud <APAINCHAUD@mitre.org>
Subject: January 14 Manufacturer Call Question Log

Hi All,

Please see the January 14 Manufacturer Technical Call materials below and attached:

Question Log: (b)(6)

Attendee Report: (b)(6)

Zoom Q&A: (b)(6)

Recording: (b)(6)

Let us know if you have any questions. We will follow up with the transcript and summary next week!

Thank you,

Devon

Devon Lara, MPH

she | ella

Health Program Analysis and Transformation

Division of Healthcare Payment, Innovation & Quality

The Health FFRDC

Work Cell: (b)(6)

From:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent:	3/1/2024 3:56:43 PM -0500
To:	"Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Li, Tina (CMS/CM)" <ting.li@cms.hhs.gov>
CC:	"Hunter, Kaitlin (CMS/CM)" <Kaitlin.Hunter@cms.hhs.gov>
BCC:	
Subject:	FW: FW: Medicare Drug Price Negotiation Program – MFP Counteroffer for Jardiance
Attachments:	OrganizationLogo.png; Boehringer Ingelheim Email Post-Counteroffer.pdf

Out of Scope

From: Marsh,Christine (HP MA) BIP-US-R <christine.marsh@boehringer-ingelheim.com>
Sent: Friday, March 1, 2024 3:35 PM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Cc: Edele,Audra (HP MA) BIP-US-R <audra.edele@boehringer-ingelheim.com>; Gemma,Katye (LEG HP) BI-US-R <katye.gemma@boehringer-ingelheim.com>; Kowalski,Dr.,Jennifer (HP Bu Ops) BIP-US-R <jennifer.kowalski@boehringer-ingelheim.com>
Subject: Medicare Drug Price Negotiation Program – MFP Counteroffer for Jardiance
Sensitivity: Confidential

Marsh,Christine (HP MA) BIP-US-R (christine.marsh@boehringer-ingelheim.com)
has sent you a protected message.

Read the message

This e-mail is confidential and may also be legally privileged. If you are not the intended recipient please reply to sender, delete the e-mail and do not disclose its contents to any person. Any unauthorized review, use, disclosure, copying or distribution is strictly prohibited. Please find more information at https://guides.boehringer-ingelheim.com how to manage encrypted emails with Boehringer-Ingelheim.

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Privacy Statement

Learn More on email encryption.
Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

From: "Richardson [she/her], Erin (CMS/OA)" (b)(6)

(b)(6)

Sent: 1/16/2025 10:41:13 AM -0500
To: CMS OA Incoming Controls <OAIncomingControls@cms.hhs.gov>
CC:
BCC:
Subject: FW: FW: Follow-up: Ensuring Insulin Availability in the United States
Attachments: image001.png; image002.png; Humalog CMS Letter - 1.7.2025.pdf

Out of Scope

From: Derek L Asay <asay_derek_l@lilly.com>
Sent: Wednesday, January 15, 2025 5:39:23 PM
To: Brooks-LaSure, Chiquita (CMS/OA) <Chiquita.Brooks-LaSure@cms.hhs.gov>; meena.seshamani@cms.hhs.gov <meena.seshamani@cms.hhs.gov>
Cc: Harris, Will (CMS/CCSQ) <William.Harris@cms.hhs.gov>
Subject: Follow-up: Ensuring Insulin Availability in the United States

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

I am following up on the attached letter Lilly's Chair and CEO, Dave Ricks, sent to you last week regarding insulin availability in the United States. As highlighted in the letter, we wish to bring to your attention the many reasons that Humalog legally cannot and prudentially should not be included on the list of "negotiation-eligible drugs" for initial price applicability year (IPAY) 2027. We would welcome the opportunity to meet with you or your staff to discuss this issue further.

Best regards,

Derek

Derek Asay

Senior Vice President, Government Strategy and Federal Accounts

(b)(6) (mobile)

derek.asay@lilly.com

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From:	"Rice, Cheri (CMS/CM)" <Cheri.Rice@cms.hhs.gov>
Sent:	1/22/2025 10:43:48 AM -0500
To:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>
CC:	"Hutchinson, Claire (CMS/CM)" <claire.hutchinson@cms.hhs.gov>
BCC:	
Subject:	RE: RE: Urgent issue regarding Otzela® (apremilast) inclusion on IPAY 2027 selected drug list
Attachments:	image001.png; image002.png; image003.png; image004.png; image005.png; image006.png; image007.png

Out of Scope

From: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Sent: Tuesday, January 21, 2025 9:55 PM
To: Rice, Cheri (CMS/CM) <Cheri.Rice@cms.hhs.gov>
Cc: Hutchinson, Claire (CMS/CM) <claire.hutchinson@cms.hhs.gov>
Subject: FW: Urgent issue regarding Otzela® (apremilast) inclusion on IPAY 2027 selected drug list

Out of Scope

From: Gawlik, Yola <ygawlik@amgen.com>
Sent: Tuesday, January 21, 2025 7:36 PM
To: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Cc: Mandel, Giana <gmandel@amgen.com>
Subject: Urgent issue regarding Otzela® (apremilast) inclusion on IPAY 2027 selected drug list

Chris and Laura,

We write to raise an urgent issue regarding the IPAY 2027 selected drug list, as it appears our drug Otezla was erroneously included. While we do not have visibility into the process CMS followed, and thus cannot say with certainty why this error occurred, we note that the list excludes two other drugs—Creon and Humalog—that, under CMS's guidance, appear to have higher Medicare Part D gross spending during the relevant period than Otezla and otherwise appear to meet the "Qualifying Single Source Drug" definition that CMS created. It's our understanding, for example, that there are no approved and marketed 351(k) biosimilar products that list either Creon or Humalog as their reference product in the Purple Book.

We would like to request that CMS issue a corrected list for IPAY 2027 and would appreciate the opportunity to speak with you about this as soon as possible. We will make ourselves

available at your earliest convenience, and we thank you in advance for your prompt attention to this important matter.

Regards,

Yola Gawlik

Yola Gawlik (she, her, hers)

Executive Director | U.S. Health Policy and Reimbursement

Global Government Affairs and Policy

m: (b)(6)

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Citations - Question 28: Therapeutic Impact and Comparative Effectiveness

1. Data on file, REF-98560. Aynilian P. AbbVie Inc. 2023.
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8. Brown JR, Eichhorst B, Hillmen P, Jurczak W, Kaźmierczak M, Lamanna N, O'Brien SM, Tam CS, Qiu L, Zhou K, Simkovic M, Mayer J, Gillespie-Twardy A, Ferrajoli A, Ganly PS, Weinkove R, Grosicki S, Mital A, Robak T, Osterborg A, Yimer HA, Salmi T, Wang MDY, Fu L, Li J, Wu K, Cohen A, Shadman M. Zanubrutinib or ibrutinib in relapsed or refractory chronic lymphocytic leukemia. New Engl J Med. 2023 Jan 26;388(4):319-332.
9. Hillmen P, Eichhorst B, Brown JR, Lamanna N, O'Brien SM, Tam CS, Qiu L, Kazmierczak M, Zhou K, Šimkovič M, Mayer J, Gillespie-Twardy A, Shadman M, Ferrajoli A, Ganly PS, Weinkove R, Grosicki S, Mital A, Robak T, Österborg A, Yimer HA, Salmi T, Ji M, Yecies J, Idoine A, Wu K, Huang J, Jurczak W. Zanubrutinib versus ibrutinib in relapsed/refractory chronic lymphocytic leukemia and small lymphocytic lymphoma: interim analysis of a randomized phase III trial. J Clin Oncol. 2023 Feb;41(5):1035-1045.
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Investigators. Ibrutinib as initial therapy for patients with chronic lymphocytic leukemia. N Engl J Med. 2015 Dec 17;373(25):2425-37.
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18. Byrd JC, Hillmen P, O'Brien S, Barrientos JC, Reddy NM, Coutre S, Tam CS, Mulligan SP, Jaeger U, Barr PM, Furman RR, Kipps TJ, Thornton P, Moreno C, Montillo M, Pagel JM, Burger JA, Woyach JA, Dai S, Vezan R, James DF, Brown JR. Long-term follow-up of the RESONATE phase 3 trial of Ibrutinib vs ofatumumab. Blood. 2019 May 9;133(19):2031-2042.
19. Brown JR, Eichhorst B, Hillmen P, Jurczak W, Kaźmierczak M, Lamanna N, O'Brien SM, Tam CS, Qiu L, Zhou K, Simkovic M, Mayer J, Gillespie-Twardy A, Ferrajoli A, Ganly PS, Weinkove R, Grosicki S, Mital A, Robak T, Osterborg A, Yimer HA, Salmi T, Wang MDY, Fu L, Li J, Wu K, Cohen A, Shadman M. Zanubrutinib or ibrutinib in relapsed or refractory chronic lymphocytic leukemia. New Engl J Med. 2023 Jan 26;388(4):319-332.
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23. Munir T, Genovez V, Genestier V, Ryan K, Liljas B, Gaitonde P. Cost-effectiveness of acalabrutinib regimens in treatment-naïve chronic lymphocytic leukemia in the United States. Expert Rev Pharmacoecon Outcomes Res. 2023 Jun;23(5):579-589.
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combination with obinutuzumab in first-line, unfit chronic lymphocytic leukemia in the United States. J Manag Care Spec Pharm. 2021 Nov;27(11):1532-1544.
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From:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent:	10/23/2024 4:07:32 PM -0400
To:	"Boone, Chanelle (CMS/CM)" <Chanelle.Boone@cms.hhs.gov>; "Wojcicki, Michelle (CMS/CM)" <michelle.wojcicki2@cms.hhs.gov>; "Kane, Corden (CMS/CM)" <corden.kane2@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>
CC:	
BCC:	
Subject:	FW: FW: IPAY 2026 Pre-Disclosure Notice of Primary Manufacturer's Responses
Attachments:	Sitagliptin_Januvia_Pre-Disclosure Notice_Addl. Matl. to MFP Public Explanation.pdf

Out of Scope

From: Seris, Mark <mark_seris@merck.com>
Sent: Wednesday, October 23, 2024 10:51 AM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Cc: Robinson, Kate <kate.robinson@merck.com>; Burgess, Breon <breon_burgess@merck.com>; Bergmann, John W. <john_bergmann@merck.com>
Subject: IPAY 2026 Pre-Disclosure Notice of Primary Manufacturer's Responses
Importance: High

Dear Medicare Drug Rebate and Negotiations Group,

Merck is in receipt of your letter dated October 18, 2024, allowing for a review of the materials that may be released to the public related to the Maximum Fair Price Explanation for JANUVIA (Sitagliptin). Merck is actively working on reviewing CMS' proposed redactions to properly propose changes to CMS' draft, if necessary.

To be thorough, Merck will conduct various reviews of the recommendations, and will ensure that any proposed changes are appropriately justified. Due to the size of the submission, Merck is requesting an extension of the 10-business-day deadline and requests that the due date be moved to **November 15, 2024**.

Merck would greatly appreciate a prompt response from CMS to this request.

Regards,
Mark

Mark Seris | Executive Director, Finance - Customer Contract Management | Merck Sharp & Dohme LLC

p. 267-305-6850 | mark_seris@merck.com | 351 N. Sumneytown Pike, Mailstop UG4AB-15, North Wales, PA 19454

A

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Friday, October 18, 2024 1:50 PM
To: Robinson, Kate <kate.robinson@merck.com>; Burgess, Breon <breon_burgess@merck.com>; Seris, Mark <mark_seris@merck.com>; Bergmann, John W. <john_bergmann@merck.com>
Subject: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box
Importance: High

EXTERNAL EMAIL– Use caution with any links or file attachments.

Dear Merck Sharp Dohme, 'a0

CMS is providing an opportunity for pre-disclosure review of manufacturer-submitted materials. Please see the attached letter for details and instructions.

The individuals representing Merck Sharp Dohme who currently have access to the CMS Box folder located at (b)(6) for Januvia, should receive a notification today from noreply@box.com that contains a link to materials CMS has added to your CMS Box folder, within the folder titled "Pre-Disclosure Review", for your **immediate** review.

To request access for additional individuals or to request removal of access for any individuals to the Box folder, please respond to this email with their names and email addresses, and CMS will share with them a Box access invitation or remove Box access, as appropriate. 'a0 'a0

Sincerely, 'a0

Medicare Drug Rebate and Negotiations Group

This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (126 East Lincoln Ave., P.O. Box 2000, Rahway, NJ USA 07065) and/or its affiliates, that may be confidential, proprietary copyrighted and/or legally privileged. (Direct contact information for affiliates is available at - Contact us - MSD.) It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

From: "Ritter, Christina (CMS/CM)" (b)(6)

(b)(6)

Sent: 7/15/2024 12:53:42 PM -0400
To: "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Cole (she/her), Rebecca (CMS/CM)" <Rebecca.Cole@cms.hhs.gov>
CC:
BCC:
Subject: RE: RE: items for Kristi tomorrow
Attachments: Re: Meeting with CMS and several stakeholders (akin to an IPAY 26 coalition) most impacted by IPAY 26 to advance the requirements for MFP Effectuation?

Out of Scope hed.

From: Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>
Sent: Monday, July 15, 2024 11:59 AM
To: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Cole (she/her), Rebecca (CMS/CM) <Rebecca.Cole@cms.hhs.gov>
Subject: RE: items for Kristi tomorrow

Out of Scope

From: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Sent: Monday, July 15, 2024 11:57 AM
To: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>; Cole (she/her), Rebecca (CMS/CM) <Rebecca.Cole@cms.hhs.gov>
Subject: items for Kristi tomorrow

Out of Scope

Out of Scope

Appointment Title:	External Call: CMS/BMS (F/U from Nov 14 Call)
Organizer:	Weiss, Rachel (CMS/CM)
Attendees:	Tucker, Caroline; Folsom, Brennan (CMS/CM); Coster, John (CMS/CM); Li, Tina (CMS/CM); Williams, Alexandra; Knott, William; Hunter, Kaitlin (CMS/CM); Ritter, Christina (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Brock, Janet (CMS/CM); Verb, Katie
Location:	https://cms.zoomgov.com/j (b)(6) pwd= (b)(6) 1
Start Time:	12/10/2024 2:30:00 PM -0500
End Time:	12/10/2024 3:00:00 PM -0500
Reminder Time:	12/10/2024 2:15:00 PM -0500
Reminder Set:	true
Duration:	30 minutes
Is Recurring:	false
Reccurrance Type:	Not
Reccurrance Pattern:	
Response Status:	5
Busy Status:	Tentative
Attachments:	image001.png

Hi Rachel,

Thank you so much for your assistance in helping us schedule our November 14th meeting with CMS. Our team really appreciated the time and discussion. We were hoping to engage the Negotiation Team again in early December in advance of IPAY 2027 drug selection for a 30-minute meeting and would be grateful if you could help us in coordinating that as well. Please let me know what additional information I can provide, and I would be happy to do so.

Thank you in advance! And have a wonderful Thanksgiving!

Caroline

Caroline P. Tucker

Director | Executive Branch Strategy

US Policy & Government Affairs

Email: caroline.tucker@bms.com

Mobile: (b)(6)

CARIE Spangler is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

https://cms.zoomgov.com (b)(6) 'pwd (b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

+16692545252, US (San Jose)

+16468287666, (b)(6) US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

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833 435 1820 US Toll-free

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Meeting ID: (b)(6)

Find your local number: https://cms.zoomgov.com/ (b)(6)

Join by SIP

Password: (b)(6)

sip: (b)(6) @ (b)(6) com

This meeting may be recorded. The host is responsible for maintaining any official recordings/transcripts of this meeting. If recorded, this meeting becomes an official record and shall be retained by the host in their files for 3 years or if longer needed for agency business. If a recording intends be fully transcribed or is being captured for the purpose of creating meeting minutes, the host shall retain the record in their files for 3 years or if no longer needed for agency business, whichever is later.

From:	"Kane, Corden (CMS/CM)" <corden.kane2@cms.hhs.gov>
Sent:	10/29/2024 2:52:52 PM -0400
To:	"Hess, Matthew (CMS/CM)" <matthew.hess@cms.hhs.gov>; "Boone, Chanelle (CMS/CM)" <Chanelle.Boone@cms.hhs.gov>; "Wojcicki, Michelle (CMS/CM)" <michelle.wojcicki2@cms.hhs.gov>
CC:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>; "Lynn, Nicholas (CMS/CM)" <nicholas.lynn@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; "Kehres, Katherine (CMS/CM)" <katherine.kehres1@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>
BCC:	
Subject:	RE: RE: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box
Attachments:	image001.png

Out of Scope

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Tuesday, October 29, 2024 2:45 PM
To: Boone, Chanelle (CMS/CM) <Chanelle.Boone@cms.hhs.gov>; Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>; Wojcicki, Michelle (CMS/CM) <michelle.wojcicki2@cms.hhs.gov>
Subject: FW: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box

Out of Scope

From: Caprisecca, Odalys <odalys.caprisecca@novartis.com>
Sent: Tuesday, October 29, 2024 9:35 AM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Subject: Re: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box

Good Morning

Can you please provide guidance on where you would like the updated documents uploaded to.

Should I create a new folder on the main directory or a folder in the Pre-Disclosure Review folder.

Thank you in advance for your guidance

Thank you,

Odalys

Odalys Caprisecca
Vice President, Managed Markets Finance

MANAGED MARKETS FINANCE / US PHARMA

Novartis Pharmaceuticals Corporation

One Health Plaza

East Hanover, NJ 07936-1080

M + (b)(6)

odalys.caprisecca@novartis.com

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Friday, October 18, 2024 2:16 PM
To: Caprisecca, Odalys <odalys.caprisecca@novartis.com>; Nelson, Lisa-2 <lisa-2.nelson@novartis.com>
Subject: [For Immediate Review] CMS Medicare Drug Price Negotiation Program IPAY 2026: Notification of Files Added to Box

This Message Is From an External Sender

This message came from outside your organization.

Dear Novartis Pharms Corp, â€¯

CMS is providing an opportunity for pre-disclosure review of manufacturer-submitted materials. Please see the attached letter for details and instructions.

The individuals representing Novartis Pharms Corp who currently have access to the CMS Box folder located atâ€¯

(b)(6)

for Entresto, should receive a notification today from noreply@box.com that contains a link to materials CMS has added to your CMS Box folder, within the folder titled â€œPre-Disclosure Reviewâ€□, for your **immediate** review.

To request access for additional individuals or to request removal of access for any individuals to the Box folder, please respond to this email with their names and email addresses, and CMS will share with them a Box access invitation or remove Box access, as appropriate.â€¯â€¯

Sincerely,â€¯

Medicare Drug Rebate and Negotiations Groupâ€¯

From:	CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent:	7/2/2024 9:00:24 PM -0400
To:	"Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>
CC:	
BCC:	
Subject:	FW: FW: [EXTERNAL] Medicare Drug Price Negotiation Program Negotiation Meeting Associated Offer Available for Imbruvica
Attachments:	image001.png; image002.png; AbbVie-Pharmacyclics Nondisclosure Confirmation - signed.pdf; AbbVie-Pharmacyclics Medicare Drug Price Negotiaton Agreement Letter - signed.pdf; DrugPriceNegotiationAgreement_20240702202030 MCS_Redacted.pdf

Out of Scope

From: Staff, Michael C <michael.staff@abbvie.com>
Sent: Tuesday, July 2, 2024 8:37 PM
To: CMS hpms <hpms@cms.hhs.gov>; CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>; Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>
Cc: Skup, Martha <martha.skup@abbvie.com>
Subject: RE: [EXTERNAL] Medicare Drug Price Negotiation Program Negotiation Meeting Associated Offer Available for Imbruvica

Hello,

As CMS has required, I signed the "Medicare Drug Price Negotiation Program Agreement" in HPMS within three business days of our meeting. Please see attached.

Also, as CMS has requested, please find attached a written confirmation that pre-disclosure notification is required.

Sincerely,

Mike Staff

MICHAEL STAFF

Vice President, Inflation Reduction Act (IRA) Product and Channel Strategies

AbbVie

26525 Riverwoods Blvd

3C 301 06

Mettawa, IL 60045

OFFICE 847-937-9887

CELL (b)(6)

EMAIL michael.staff@abbvie.com

abbvie.com

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From: hpms@cms.hhs.gov <hpms@cms.hhs.gov>
Sent: Thursday, June 27, 2024 2:38 PM
To: Skup, Martha <martha.skup@abbvie.com>; Staff, Michael C <michael.staff@abbvie.com>; Akintade, Latif <latif.akintade@abbvie.com>; Buckbee, Kevin K <kevin.buckbee@abbvie.com>
Cc: IRARebateandNegotiation@cms.hhs.gov

Subject: [EXTERNAL] Medicare Drug Price Negotiation Program Negotiation Meeting Associated Offer Available for Imbruvica

Thank you for participating in the recent negotiation meeting with representatives from the Centers for Medicare & Medicaid Services (CMS). CMS has made available a written offer that incorporates the potential Maximum Fair Price we discussed related to the following: Imbruvica

Please log in to CMS HPMS to review this negotiation meeting associated offer. Please respond by either accepting the offer by signing the Medicare Drug Price Negotiation Program Agreement Negotiated Maximum Fair Price Addendum ("Addendum") that incorporates the potential Maximum Fair Price we discussed or rejecting this negotiation meeting associated offer.

After reviewing the offer, a signatory user may select one of the buttons at the bottom of the offer to either navigate to the Addendum or to reject this offer.

For technical assistance, please contact the CMS HPMS Help Desk at either hpms@cms.hhs.gov or 1-800-220-2028. For other questions, please email IRARebateandNegotiation@cms.hhs.gov with the following subject line: "Negotiation Meeting Associated Offer."

This e-mail was generated by the CMS Health Plan Management System (HPMS).

For technical assistance, contact the HPMS Help Desk at hpms@cms.hhs.gov or 1-800-220-2028.

From:	"Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>
Sent:	12/5/2024 8:07:40 AM -0500
To:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Coster, John (CMS/CM)" <John.Coster@cms.hhs.gov>
CC:	"Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>
BCC:	
Subject:	RE: RE: MDRNG OGC meeting 12/04
Attachments:	Question on Comment on Treatment of Maximum Fair Price in ASP and MDRP

Out of Scope

From: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Sent: Wednesday, December 4, 2024 8:42 PM

To: Eakle, Elizabeth (CMS/CM) <Elizabeth.Eakle@cms.hhs.gov>; Campbell, Sara (CMS/CM) <sara.campbell@cms.hhs.gov>; Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>; Kane, Elizabeth (CMS/CM) <elizabeth.kane1@cms.hhs.gov>; McCormick, Michael (CMS/CM) <Michael.McCormick@cms.hhs.gov>; Yip, Rebecca (CMS/CM) <rebecca.yip@cms.hhs.gov>; Eschliman, Brede (CMS/CM) <brede.eschliman1@cms.hhs.gov>; Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>; Heider, Daniel (CMS/CM) <daniel.heider@cms.hhs.gov>; Rosenberg, Corey (CMS/CM) <Corey.Rosenberg@cms.hhs.gov>; Daniel, Elisabeth (CMS/CM) <elisabeth.daniel@cms.hhs.gov>; Garrigan, Thomas (CMS/CM) <thomas.garrigan@cms.hhs.gov>; Li, Tina (CMS/CM) <ting.li@cms.hhs.gov>; Coster, John (CMS/CM) <John.Coster@cms.hhs.gov>
Cc: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>
Subject: MDRNG OGC meeting 12/04

Out of Scope

From:	"Denemark, Cindy (CMS/CMCS)" <Cynthia.Denemark@cms.hhs.gov>
Sent:	12/5/2024 11:27:00 AM -0500
To:	"Szafara (she/her), Kelly (CMS/CM)" <kelly.szafara1@cms.hhs.gov>
CC:	"Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>; "Kennedy, Laura (CMS/CM)" <Laura.Kennedy@cms.hhs.gov>; "Alemi, Omar (CMS/CMCS)" <Omar.Alemi@cms.hhs.gov>; "Traugott, Cathy (CMS/CMCS)" <catherine.traugott@cms.hhs.gov>; "Morgan, Mickey (CMS/CMCS)" <Mickey.Morgan1@cms.hhs.gov>
BCC:	
Subject:	RE: RE: Question on Comment on Treatment of Maximum Fair Price in ASP and MDRP

Out of Scope

From: Szafara (she/her), Kelly (CMS/CM) <kelly.szafara1@cms.hhs.gov>
Sent: Wednesday, December 4, 2024 10:58 AM
To: Denemark, Cindy (CMS/CMCS) <Cynthia.Denemark@cms.hhs.gov>
Cc: Daniel, Elisabeth (CMS/CM) <elisabeth.daniel@cms.hhs.gov>; Garrigan, Thomas (CMS/CM) <thomas.garrigan@cms.hhs.gov>; Kennedy, Laura (CMS/CM) <Laura.Kennedy@cms.hhs.gov>
Subject: Question on Comment on Treatment of Maximum Fair Price in ASP and MDRP

Out of Scope

Out of Scope

Out of Scope

From:	"Ritter, Christina (CMS/CM)" (b)(6) (b)(6)
Sent:	12/10/2024 8:36:25 AM -0500
To:	"Hutchinson, Claire (CMS/CM)" <claire.hutchinson@cms.hhs.gov>
CC:	
BCC:	
Subject:	FW: FW: AbbVie Letter to CMS (Ineligibility of CREON for IRA IPAY 2027)
Attachments:	image001.gif; AbbVie Letter to CMS - Ineligibility of CREON for IRA IPAY 2027 - 12-9-24 - FINAL.pdf

From: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Sent: Monday, December 9, 2024 8:33 PM
To: Yip, Rebecca (CMS/CM) <rebecca.yip@cms.hhs.gov>; Eschliman, Brede (CMS/CM) <brede.eschliman1@cms.hhs.gov>; Heider, Daniel (CMS/CM) <daniel.heider@cms.hhs.gov>; Rosenberg, Corey (CMS/CM) <Corey.Rosenberg@cms.hhs.gov>
Cc: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Subject: FW: AbbVie Letter to CMS (Ineligibility of CREON for IRA IPAY 2027)

Out of Scope

From: Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>
Sent: Monday, December 9, 2024 8:14 PM
To: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>; Hunter, Kaitlin (CMS/CM) <Kaitlin.Hunter@cms.hhs.gov>; Rice, Cheri (CMS/CM) <Cheri.Rice@cms.hhs.gov>
Subject: Fw: AbbVie Letter to CMS (Ineligibility of CREON for IRA IPAY 2027)

Out of Scope

From: Shiraki, Matt <matt.shiraki@abbvie.com>
Sent: Monday, December 9, 2024 7:05:24 PM
To: Blum, Jonathan (CMS/OA) <Jonathan.Blum@cms.hhs.gov>; Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>

Cc: Kennedy, Hayden R <hayden.kennedy@abbvie.com>; Shiraki, Matt <matt.shiraki@abbvie.com>
Subject: AbbVie Letter to CMS (Ineligibility of CREON for IRA IPAY 2027)

Dear Principal Deputy Administrator Blum and Dr. Seshamani:

On behalf of Hayden Kennedy (Vice President, Global Policy & U.S. Access Strategies, Government Affairs, AbbVie), I have attached AbbVie's letter to CMS regarding ineligibility of CREON for IRA IPAY 2027. Please confirm receipt.

Thank you for reviewing our letter, and please let me know if you have any questions.

Best,
Matt

MATT SHIRAKI

Director, Therapeutic Area Strategies (Oncology & Specialty)
Government Affairs

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Appointment Title:	External Call: J&J RE IRA
Organizer:	Seshamani, Meena (CMS/OA)
Attendees:	Duran, Vanessa (CMS/CM); Hunter, Kaitlin (CMS/CM); Weiss, Rachel (CMS/CM); Ritter, Christina (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Brock, Janet (CMS/CM); Coster, John (CMS/CM); Daniel, Elisabeth (CMS/CM); Garrigan, Thomas (CMS/CM); McCormick, Michael (CMS/CM); Heider, Daniel (CMS/CM); Rosenberg, Corey (CMS/CM); Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>; Schmidt, Calvin [JJCUS] <CSchmid3@its.jnj.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>; Folsom, Brennan (CMS/CM)
Location:	https://cms.zoomgov.com (b)(6) pwd: (b)(6) 1
Start Time:	11/14/2024 3:30:00 PM -0500
End Time:	11/14/2024 4:00:00 PM -0500
Reminder Time:	11/14/2024 3:15:00 PM -0500
Reminder Set:	true
Duration:	30 minutes
Is Recurring:	false
Reccurrance Pattern:	
Response Status:	5
Busy Status:	Tentative

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Sent: Thursday, October 24, 2024 9:56 AM
To: Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>; Blum, Jonathan (CMS/OA) <Jonathan.Blum@cms.hhs.gov>
Cc: Schmidt, Calvin [JJCUS] <CSchmid3@its.jnj.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>
Subject: Request to meet with J&J _ IRA

Hi Jon and Meena, I hope you both are well. Thank you and your CMS IRA team for the engagement over the past year. Now that CMS has released the final IRA guidance for IPAY 2026 and 2027, Calvin and the J&J team is requesting to meet with you to cover the following agenda as we collectively prepare for January 1, 2026. We value this time with you and appreciate meeting at your earliest convenience.

Our goal is to discuss 1) Operational readiness for Jan 1, 2026, and our most pressing asks of the Agency, 2) Advance our aligned goals related to Medicare beneficiary

access for selected drugs and the formulary review process, including sharing insights, and 3), to offer our feedback on the public explanation process ahead of 2025.

Thank you again, Meena and John. We look forward to the discussion (live or virtual).

Jackie

Kind Regards,

Jacqueline Roche

Head Payment and Delivery & Global Policy Institute

Mobile: (b)(6)

Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

From:	"Hunter, Kaitlin (CMS/CM)" <Kaitlin.Hunter@cms.hhs.gov>
Sent:	10/23/2024 3:01:08 PM -0400
To:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Roche, Jacqueline [JJCUS]" <jroche8@its.jnj.com>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Spangler, Carie (CMS/CM)" <Carie.Spangler@cms.hhs.gov>
CC:	"Donnelly, Robert [JJCUS]" <RDonnel4@ITS.JNJ.com>; "Schaeffer, John [HCSUS]" <JSchaeff@ITS.JNJ.com>; "Weiss, Rachel (CMS/CM)" <rachel.weiss@cms.hhs.gov>
BCC:	
Subject:	RE: RE: Request to meet with J&J _ 30 minutes on IRA selection criteria

Hi Jackie,

Thanks for reaching out. A deck in advance would be great. Do you all have 30 minutes on November 5 from 2-3 PM or November 7 from 1:30-2 PM?

@Spangler, Carie (CMS/CM)- If any of those times work for J&J, can you send an invite for me, Rachel, Chris, Lara, Tina Li, Dan, Corey, Elisabeth, TJ, Rebecca Y., and Brede?

Thanks,

Kaitlin

From: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>
Sent: Wednesday, October 23, 2024 2:11 PM
To: Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Cc: Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Hunter, Kaitlin (CMS/CM) <Kaitlin.Hunter@cms.hhs.gov>; Spangler, Carie (CMS/CM) <Carie.Spangler@cms.hhs.gov>
Subject: RE: Request to meet with J&J _ 30 minutes on IRA selection criteria

Of course, adding Kaitlin Hunter who has stepped in for Kristi Martin, and Carie Spangler to assist with scheduling. Best, Chris and Lara

---

From: Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>
Sent: Wednesday, October 23, 2024 11:58 AM

To: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Cc: Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>
Subject: Request to meet with J&J _ 30 minutes on IRA selection criteria

Hi Lara and Chris. Thank you and your CMS IRA team for the ongoing engagement. We look forward to speaking with the CMS operational team on the 28th, alongside several other manufacturers.

Separately, with the release of the final IRA guidance for IPAY 2026 and 2027, the J&J team requests to meet to confirm our understanding of applying the IRA criteria for selected drugs to J&J assets (the QSSD interpretation). We advanced a similar conversation in July 2023 and found it very constructive. We look forward to walking you through our interpretation to confirm our understanding as soon as possible.

Thank you in advance and happy to help with scheduling, 30 minutes is sufficient. We can send the deck in advance (if preferred).

Thank you,

Jackie

Kind Regards,

Jacqueline Roche

Head Payment and Delivery & Global Policy Institute

Mobile: (b)(6)

Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

Meeting Title:	External Call: J&J RE IRA
From:	"Spangler, Carie (CMS/CM)" <Carie.Spangler@cms.hhs.gov>
Sent:	11/1/2024 10:21:27 AM -0400
To:	"Duran, Vanessa (CMS/CM)" <Vanessa.Duran@cms.hhs.gov>; "Hunter, Kaitlin (CMS/CM)" <Kaitlin.Hunter@cms.hhs.gov>; "Weiss, Rachel (CMS/CM)" <rachel.weiss@cms.hhs.gov>; "Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Coster, John (CMS/CM)" <John.Coster@cms.hhs.gov>; "Daniel, Elisabeth (CMS/CM)" <elisabeth.daniel@cms.hhs.gov>; "Garrigan, Thomas (CMS/CM)" <thomas.garrigan@cms.hhs.gov>; "McCormick, Michael (CMS/CM)" <Michael.McCormick@cms.hhs.gov>; "Heider, Daniel (CMS/CM)" <daniel.heider@cms.hhs.gov>; "Rosenberg, Corey (CMS/CM)" <Corey.Rosenberg@cms.hhs.gov>; Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>; Schmidt, Calvin [JJCUS] <CSchmid3@its.jnj.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>; "Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>
CC:	
BCC:	
Attendees:	Duran, Vanessa (CMS/CM); Hunter, Kaitlin (CMS/CM); Weiss, Rachel (CMS/CM); Ritter, Christina (CMS/CM); Strawbridge (she/her), Lara (CMS/CM); Brock, Janet (CMS/CM); Coster, John (CMS/CM); Daniel, Elisabeth (CMS/CM); Garrigan, Thomas (CMS/CM); McCormick, Michael (CMS/CM); Heider, Daniel (CMS/CM); Rosenberg, Corey (CMS/CM); Roche, Jacqueline [JJCUS] <jroche8@its.jnj.com>; Schmidt, Calvin [JJCUS] <CSchmid3@its.jnj.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>; Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>; Folsom, Brennan (CMS/CM)
Location:	https://cms.zoomgov.com/j (b)(6) pwd= (b)(6) 1
Start Time:	11/14/2024 3:30:00 PM -0500
End Time:	11/14/2024 4:00:00 PM -0500
Duration:	30 minutes
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Is Recurring:	false
Recurrence Pattern:	
Busy Status:	Tentative

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Sent: Thursday, October 24, 2024 9:56 AM

To: Seshamani, Meena (CMS/OA) <Meena.Seshamani@cms.hhs.gov>; Blum, Jonathan (CMS/OA) <Jonathan.Blum@cms.hhs.gov>

Cc: Schmidt, Calvin [JJCUS] <CSchmid3@its.jnj.com>; Schaeffer, John [HCSUS] <JSchaeff@ITS.JNJ.com>;

Donnelly, Robert [JJCUS] <RDonnel4@ITS.JNJ.com>; Blevins, Lee [SCGUS] <LBlevins@its.jnj.com>
Subject: Request to meet with J&J _ IRA

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Thank you again, Meena and John. We look forward to the discussion (live or virtual).

Jackie

Kind Regards,

Jacqueline Roche

Head Payment and Delivery & Global Policy Institute

Mobile: (b)(6)

Address: 1350 I (eye) Street, N.W. Washington, D.C. 20005, Suite 1210

From: Lockwood, Candice (CMS/CM)
To: Folsom, Brennan (CMS/CM); Kane, Corden (CMS/CM); Yip, Rebecca (CMS/CM); Eschliman, Brede (CMS/CM); Hendrick, Franklin (CMS/CM); Callies-Virshup, Michelle (CMS/CM); Maynard, John (CMS/CM)
Subject: FW: Outreach – Additional NDC-11s Identified – Response Needed
Date: Wednesday, April 3, 2024 10:38:34 AM

Out of Scope

From: Robinson, Kate <kate.robinson@merck.com>
Sent: Wednesday, April 3, 2024 10:06 AM
To: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Cc: Darling, Erin Lewis <erin_darling@merck.com>; Seris, Mark <mark_seris@merck.com>; Burgess, Breon <breon_burgess@merck.com>
Subject: RE: Outreach – Additional NDC-11s Identified – Response Needed

Proprietary

To: Medicare Drug Rebate and Negotiations Group,

Merck Sharp & Dohme LLC ("Merck") is in receipt of your outreach attached regarding NDC 50090-3472-00. Below is our response to the information you requested:

NDC-11	Marketed/Controlled by the Primary Manufacturer or a Secondary Manufacturer (Y/N)	Sample Package NDC (Y/N)
50090-3472-00	NO	UNKNOWN

Merck does not maintain a contractual relationship for JANUVIA® with the entity selling under labeler code 50090, which is not registered with Merck. Because this entity is not listed as a manufacturer in the JANUVIA® labeling and does not maintain a contractual relationship with Merck, it does not meet the definition of a "Secondary Manufacturer," under section 40 of the Revised Guidance. Additionally, Merck is unaware of whether NDC 50090-3472-00 is a sample or trade package.

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b)(3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.

Please do not hesitate to contact us if you have any additional questions.

Regards,
Kate Robinson
Cell (b)(6)

From: CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov>
Sent: Monday, April 1, 2024 11:22 AM
To: Seris, Mark <mark_seris@merck.com>; Robinson, Kate <kate.robinson@merck.com>; Burgess, Breon <breon_burgess@merck.com>
Subject: Outreach – Additional NDC-11s Identified – Response Needed

EXTERNAL EMAIL– Use caution with any links or file attachments.
Merck Sharp Dohme:

Please find attached a letter regarding additional NDC-11s that we recently identified. We request your review and responses no later than April 8, 2024 at 5pm ET.

Regards,

Medicare Drug Rebate and Negotiations Group

This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (126 East Lincoln Ave., P.O. Box 2000, Rahway, NJ USA 07065) and/or its affiliates, that may be confidential, proprietary copyrighted and/or legally privileged. (Direct contact information for affiliates is available at - Contact us - MSD.) It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

From:	"Strawbridge (she/her), Lara (CMS/CM)" <Lara.Strawbridge@cms.hhs.gov>
Sent:	1/19/2024 10:38:24 AM -0500
To:	"Folsom, Brennan (CMS/CM)" <brennan.folsom@cms.hhs.gov>
CC:	"Ritter, Christina (CMS/CM)" <Christina.Ritter@cms.hhs.gov>; "Brock, Janet (CMS/CM)" <janet.brock2@cms.hhs.gov>; "Kane, Corden (CMS/CM)" <corden.kane2@cms.hhs.gov>
BCC:	
Subject:	RE: RE: Data Review and Manufacturer Outreach Close-out Memo
Attachments:	2024.01.12_OverviewMemo_ManufacturerDataReviewOutreach_LS.docx

Out of Scope

From: Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>
Sent: Friday, January 12, 2024 1:40 PM
To: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Cc: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>; Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>
Subject: RE: Data Review and Manufacturer Outreach Close-out Memo

Out of Scope

From: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Sent: Friday, January 12, 2024 1:34 PM
To: Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>
Cc: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Brock, Janet (CMS/CM) <janet.brock2@cms.hhs.gov>; Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>
Subject: RE: Data Review and Manufacturer Outreach Close-out Memo

Out of Scope

From: Folsom, Brennan (CMS/CM) <brennan.folsom@cms.hhs.gov>
Sent: Friday, January 12, 2024 1:33 PM
To: Strawbridge (she/her), Lara (CMS/CM) <Lara.Strawbridge@cms.hhs.gov>
Cc: Ritter, Christina (CMS/CM) <Christina.Ritter@cms.hhs.gov>; Brock, Janet (CMS/CM)

<janet.brock2@cms.hhs.gov>; Kane, Corden (CMS/CM) <corden.kane2@cms.hhs.gov>
Subject: Data Review and Manufacturer Outreach Close-out Memo

Out of Scope

(b)(6)

Bristol Myers Squibb™

DELEGATION OF AUTHORITY

WHEREAS, Bristol Myers Squibb Company (BMS) is required by law to report to the Centers for Medicare and Medicaid Services (CMS) under the Inflation Reduction Act (IRA) certain information as defined by statute for certain of its pharmaceutical products; and

WHEREAS, CMS requires that such reported information be certified by the Chief Executive Officer (CEO) or Chief Financial Officer (CFO) of BMS or an individual with the directly delegated authority to perform the certification on behalf of the CEO or CFO; and

WHEREAS, the CEO desires to delegate the authority to perform the certification required by CMS regulations to Adam Lenkowsky, Executive Vice President, Chief Commercialization Officer; and Chris Mancill, Senior Vice President and Head, Global Market Access, Pricing and Value Demonstration; and

WHEREAS, the CEO desires to delegate the authority to perform the computer certification process (for P1002) established by CMS to Linda Kamin (KMBW), Executive Director, Contract Operations and Government Reporting, and Scott Watson (WU4D), Director US Government Contract Operations, upon approval to do so from Mr. Lenkowsky or Mr. Mancill; and

WHEREAS, Mr. Lenkowsky and Mr. Mancill each has the corporate authority to perform and sign such certification; and

WHEREAS, in each instance, upon approval from Mr. Lenkowsky or Mr. Mancill, Ms. Kamin or Mr. Watson will have the corporate authorization to perform the computer certification process established by CMS;

NOW, THEREFORE, in keeping with the need to provide the certification of IRA Related Agreements and Submissions in a timely manner, the following delegation of authority is provided.

a. This delegation of authority constitutes my authorization for matters related to the IRA certifications to the CMS for all BMS Corporation labeler codes and the labeler codes of all of its wholly owned subsidiaries, including, but not limited to, Celgene Corporation, Juno Therapeutics, and MyoKardia, Inc..

b. Mr. Lenkowsky and Mr. Mancill are each authorized to take all necessary and appropriate action on my behalf in connection with the certification of the IRA Related Agreements and Submissions reported to CMS pursuant to statute or regulation, including approval and execution of such agreements and certifications.

BMS Proprietary Information - Not for Public Disclosure